

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom</b>	)	
	)	
<b>Defendants.</b>	)	

**DePuy Mitek's Response To Defendants' Objections To Magistrate's Order Granting  
DePuy Mitek, Inc.'s Motion To Preclude Arthrex, Inc. And Pearsalls Ltd. From  
Supplementing Their Expert Reports And Depositions**

## TABLE OF CONTENTS

I.	Introduction.....	1
II.	Background Factual Statement .....	2
A.	Nature Of Case.....	2
B.	Arthrex Inexplicably Delayed Until Expert Discovery Closed And Asserted That It Was Redoing Expert Discovery Because Of a “Virus” .....	2
C.	Dr. Gitis’ Mystery Virus Morphs Into “Typos”.....	4
III.	Legal Standards For Supplementing Expert Reports.....	6
A.	Contrary to Arthrex’s Assertions, The Court, Not An Expert, Controls Whether An Expert Can Supplement.....	6
B.	Contrary to Arthrex’s Assertions, An Expert is Not Permitted to Supplement Just Because It is More Than Thirty Days Before Trial .....	8
IV.	Arthrex Has Not Proven That The Magistrate Committed Clear Error.....	8
A.	Arthrex’s Argument that The Magistrate Erred By Attributing All Errors to The Mystery Virus Is Unsupported Rhetoric.....	9
B.	To the Extent the Magistrate’s Ruling Was Based on the Mystery “Virus” and Arthrex’s Conduct, Arthrex Has Not Shown Clear Error .....	9
C.	The Magistrate Did Not Commit Error Because Arthrex Failed to Satisfy Its Burden Under FED. R. CIV. P. 26(e)(1): Arthrex is Not Permitted To Supplement Because It Wishes Dr. Gitis Had Performed Better.....	10
1.	To the Extent the Magistrate’s Order Was Based On Arthrex Failing to Show That The Alleged Diameter “Typo” Was A “Typo,” Arthrex Has Not Shown Clear Error.....	10
2.	To the Extent the Magistrate’s Order Was Based On Arthrex Failing to Show That The Alleged Pliability Test Had A “Reporting Error,” Arthrex Has Not Shown Clear Error.....	13
3.	The “Typo” in the Reported Test Speed Is A Substantive Change That Was Not Before The Magistrate .....	16
D.	To the Extent the Magistrate’s Ruling Was Based on Arthrex’s Untimeliness, Arthrex Has Not Shown Clear Error.....	16
E.	To the Extent the Magistrate’s Ruling Was Based on Prejudice to Mitek, Arthrex Has Failed to Show Clear Error.....	17

F.	Mitek's Expert's Amended Supplemental Expert Report Was Before His Deposition And Provides No Refuge For Arthrex.....	18
V.	If Arthrex Is Permitted to Supplement, It Should Pay Mitek's Costs Associated with Redoing Expert Discovery.....	19
VI.	Arthrex Should Not Be Permitted To Defy the Magistrate's Order .....	19
VII.	Conclusion .....	19

## TABLE OF AUTHORITIES

### FEDERAL CASES

<i>Akeva L.L.C. v. Mizuno Corp.</i> , 212 F.R.D. 306 (M.D. N.C. 2002) .....	6, 7, 11
<i>Coles v. Perry</i> , 217 F.R.D. 1 (D. D.C. 2003).....	6
<i>DAG Enterprise, Inc. v. Exxon Mobil Corp.</i> , 226 F.R.D. 95 (D. D.C. 2005).....	7, 8, 11, 18
<i>Keener v. U.S.</i> , 181 F.R.D. 639 (D. Mont. 1998).....	16
<i>Minebea Co., Ltd. v. Papst</i> , 231 F.R.D. 3 (D. D.C. 2005).....	7
<i>Saint-Gobain Corp. v. Gemtron Corp.</i> , No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263 (W.D. Mich. May 9, 2006) .....	7, 16, 18
<i>Schumacher v. Tyson Fresh Meats, Inc.</i> , No. CIV 02-1027, 2006 WL 47504 (D. S.D. Jan. 5, 2006) .....	7
<i>Schweizer v. DEKALB Swine Breeders, Inc.</i> , 954 F. Supp. 1495 (D. Kan. 1997).....	16
<i>Sharpe v. U.S.</i> , 230 F.R.D. 452 (E.D. Va. 2005) .....	6, 8, 11, 18
<i>Tracinda Corp. v. Daimlerchrysler AG</i> , 362 F. Supp. 2d 487 (D. Del. 2005).....	7



<i>Wilson v. Sundstrand Corp.</i> , Nos. 99 C 6944, 6946, 2003 WL 22012673, at *7-*8 (N.D. Ill. Aug. 25, 2003) .....	7
---	---

## **FEDERAL RULES**

Fed. R. Civ. P. 26(e)(1) .....	10, 13
FED. R. CIV. P. 26(a)(2)(B) .....	19
Fed. R. Civ. P. 26(a)(3) .....	8
Fed. R. Civ. P. 72 .....	6

## **I. Introduction**

After expert discovery closed, Arthrex and Pearsalls (collectively “Arthrex”) initially wanted to redo technical expert reports and depositions because a “computer virus” allegedly infected the tests of one of Arthrex’s technical experts, Dr. Gitis. As this virus was a complete mystery, – and remains so today, supported by no evidence even suggesting its existence -- Mitek moved to preclude Arthrex from “supplementing” its expert reports based on this unsubstantiated virus. During the briefing before the Magistrate, Arthrex apparently realized that its virus story would not prevail, and some of its “virus” allegations morphed into so-called “typos” that needed to be corrected in the expert reports. In its reply and at the hearing, Mitek pointed out that neither the “virus” nor the “non-virus” excuses provided a basis for supplementing expert reports. On October 19, 2006, Magistrate Bowler heard argument and granted Mitek’s motion that Arthrex could not supplement its technical experts’ reports.

Now, Arthrex has totally abandoned its original “virus” allegations. Arthrex only objects to the Magistrate’s Order to the extent that Dr. Gitis, one of its technical experts, was prevented from supplementing his report based on two so-called “typos” and one “reporting” error. Arthrex raises one of Dr. Gitis’ “typos” for the first time here in its objections.

Arthrex’s only rationale for alleging that the Magistrate committed clear error is that the Magistrate was confused by Arthrex’s virus allegations. But Arthrex cites to absolutely nothing in support of its confusion allegations. Because the Magistrate ruled at the hearing and did not provide a detailed explanation for her ruling, the precise basis for her ruling is not known. But there were at least four independent reasons before the Magistrate, most of which Arthrex totally ignores, which support the Magistrate’s Order. First, the Magistrate may have been sanctioning Arthrex for its litigation tactics of alleging a computer virus with no underlying support. Second, Arthrex failed to show that the so-called typos and reporting errors were in fact “errors” or, in

any event, errors that entitled Dr. Gitis to supplement. Third, Arthrex failed to show that its proposed changes were based on information that was unavailable to Dr. Gitis between March and June 2006 when he submitted his report, supplemented it, and was deposed. Fourth, Arthrex failed to show that Mitek would not be prejudiced by Arthrex's proposed supplementation.

## **II. Background Factual Statement**

### **A. Nature Of Case**

This is a patent infringement action involving Mitek's U.S. Patent No. 5,314,446 which claims surgical sutures and suture products (Ex. 1 at 8:62-10:19). Arthrex's sale of its FiberWire suture products infringes Mitek's 446 Patent. Fact discovery closed except for some previously noticed fact depositions on February 1, 2006. Expert discovery began on March 3, 2006 and closed at the end of July 2006. Claim construction briefs and dispositive motions have been filed and were argued on September 26, 2006.

Arthrex alleges that FiberWire's surface coating "materially affects" certain alleged "basic and novel characteristics of the inventions" claimed in the 446 Patent and that, therefore, there is no infringement. Arthrex's untimely supplementation is relevant to Arthrex's argument that FiberWire's coating allegedly has a material effect on the novel and basic characteristics.

### **B. Arthrex Inexplicably Delayed Until Expert Discovery Closed And Asserted That It Was Redoing Expert Discovery Because Of a "Virus"**

In accordance with the Court's scheduling order, Mitek served an expert report from Dr. David Brookstein on March 3, 2006 showing Arthrex's infringement (Ex. 2). Arthrex responded by serving two technical expert reports on March 24, 2006. Dr. Norman Gitis, one of Arthrex's technical experts, conducted a series of tests, including pliability and knot slippage strength tests, purporting to compare certain properties of "coated" FiberWire with "uncoated" FiberWire (Ex. 3). Another of Arthrex's technical witnesses, Dr. Mukherjee, relied on Dr. Gitis' report and

opined that FiberWire does not infringe (Ex. 4 at 2, referring to Dr. Gitis' report as the "Center for Tribology, Inc." report).

Mitek's experts' initial reaction to Dr. Gitis' report was that much of it did not make sense. Therefore, on March 28, 2006, immediately after receiving Dr. Gitis' report, Mitek requested, *inter alia*, the data underlying Dr. Gitis' tests, his test protocols, and discovery of the construction and manufacturing of the samples that he tested (Ex. 5). Despite numerous requests for this information, Arthrex's counsel failed to produce it before Mitek's rebuttal expert reports were due on April 13, 2006 (Exs. 6-9). Although Arthrex's counsel had a mid-April trial, Arthrex was not able to even produce information in its possession before April 13, 2006 (*id.*). Thus, the parties agreed that Dr. Brookstein could supplement his report after Arthrex provided the requested information (Ex. 10).

In about May 2006, Arthrex produced some of the requested information, including what amounted to boxes of raw data from Dr. Gitis' tests (Ex. 11). On the same day, June 14, 2006, Mitek deposed Dr. Mukherjee and Dr. Gitis supplemented his report (Ex. 12). Mitek did not object to that supplementation as it was timely and before his deposition. Mitek then deposed Dr. Gitis on June 21, 2006.

After having analyzed Dr. Gitis' reports, his late-produced data and documents, his deposition testimony, and discovery regarding his tested samples, Mitek's expert, Dr. Brookstein, served his July 14th Supplemental Expert Report pursuant to the parties' agreement (Ex. 13). Dr. Brookstein opined that Dr. Gitis' tests were significantly flawed because, *inter alia*, he did not test samples that were really "coated" against "uncoated,"<sup>1</sup> and his testing

---

<sup>1</sup> At the end of June 2006, Mitek traveled to rural England to depose Pearsalls' witnesses to discover the exact nature of the "coated" and "uncoated" sutures tested by Dr. Gitis. As it turns out, there were significant differences between the samples tested by Dr. Gitis other than just

methodology was flawed or erroneous (*id.* at ¶¶ 8-10, 43-52). After serving his report, Dr. Brookstein served an amended report to correct a typographical error, where he mistakenly referred to the same samples as both treated and untreated and to list two documents he forgot to list in his references (Ex. 14). Like Dr. Gitis' original supplementation, Dr. Brookstein's amendment was produced before his deposition, which occurred on July 26 and 27, 2006. Expert discovery closed with Dr. Brookstein's deposition.

On July 24, 2006, just as expert discovery was closing and the parties were preparing their dispositive motions and claim construction briefs, Arthrex informed Mitek that Dr. Gitis' data may have been affected by a computer virus and that he would be redoing his tests and issuing a new expert report (Ex. 15) (emphasis added). Mitek was surprised by these "virus" allegations because all of Dr. Gitis' data was readable, and Dr. Gitis had never mentioned a "virus." Somewhat suspicious, Mitek immediately requested information regarding the alleged virus and how it affected Dr. Gitis' work (Ex. 16). Mitek has never received any information in response to this letter. On August 1, after the parties discussed the issues, Mitek advised Arthrex that it would be filing a motion to preclude Arthrex from "supplementing" its expert reports. Later that day, Arthrex informed Mitek that Dr. Gitis would be out of the country for the next couple of weeks due to an unexplained, unexpected emergency (Ex. 17).

### **C. Dr. Gitis' Mystery Virus Morphs Into "Typos"**

On August 9, 2006, Mitek filed its "Motion To Preclude Arthrex, Inc. and Pearsalls Ltd. From 'Supplementing' Their Expert Reports and Depositions" (Ex. 23). In its motion, Mitek

---

coating, as the so-called "coated" samples were also stretched and heat-treated. Because, as Dr. Mukherjee admits, heating and stretching changes suture properties (Ex. 18 at 108:25-109:5; 110:2-22) any differences determined by Dr. Gitis cannot be attributed to coating, and Dr. Gitis' work is wholly irrelevant (Ex. 14 at ¶¶ 7-10).

showed that Arthrex had not provided any proof of this so-called virus, and even if there was a virus, it was no justification for fixing Dr. Gitis' many human errors.

In its response papers, Arthrex offered no proof of a virus. Dr. Gitis has his own company and runs a testing laboratory (Ex. 3 at 1). He had employees that were involved with his tests (Ex. 19 at 82:1-5). Yet, despite these resources available to him and the alleged "detailed investigation" upon his return from his unexplained absence, no information regarding the "virus" was ever produced. Rather, Arthrex offered only Dr. Gitis' self-serving, conclusory affidavit stating that he "believed" there must have been a virus because he had no other explanation for his confusion (Ex. 20 at ¶¶13 and 16). Of course the obvious explanation was human error and/or that he does not understand how his own equipment operates. Despite any proof, Arthrex argued that this "virus" entitled it to redo certain tests (D.I. 50).

Exposed as having no proof of a virus and realizing that Mitek has correctly shown that many of Dr. Gitis' errors were not attributable to a virus, Arthrex also shifted tactics in its opposition papers. For the first time, Arthrex attributed two of Dr. Gitis' errors, his diameter measurements and pliability tests, to so-called "typographical or reporting errors" (*id.* at 8-9, n.7). Further, Arthrex tried to create an open door to supplementing by alleging in a footnote that it wanted to make so-called "garden variety" changes -- as if there is such a thing -- to correct Dr. Gitis' mistakes (*id.* at 9, n.7).

Mitek replied to Arthrex's opposition and pointed out that there was never any proof of any virus (Ex. 21 at 4). Further, Mitek showed that Dr. Gitis' so-called, typographical and reporting errors were substantive in nature, contrary to his sworn deposition testimony, wholly unsubstantiated, and failed to satisfy the conditions precedent to supplementing (*id.* at 5-11).

Then, just two days before the motion hearing, Arthrex tried a new tactic. Arthrex served supplemental expert reports from Dr. Gitis and Dr. Mukherjee in the hopes that they could somehow make it into the record without Mitek having had the chance to consider them. But these untimely reports never made it into the record. On October 19, 2006 at the hearing, the Magistrate granted Mitek's motion and ruled that Arthrex's technical experts could not supplement their expert reports.

Arthrex has now completely abandoned its "virus" tactics and has not even objected to the Magistrate's finding that Dr. Gitis cannot supplement due to this virus. Rather, Arthrex reasserts its diameter "typo" excuse, a "reporting" error with respect to its pliability testing methodology, and raises a new issue for the first time, likewise calling it a "typo."<sup>2</sup>

### **III. Legal Standards For Supplementing Expert Reports**

#### **A. Contrary to Arthrex's Assertions, The Court, Not An Expert, Controls Whether An Expert Can Supplement**

Before the Magistrate, Arthrex alleged incorrect legal standards, and it reiterates them here. Arthrex alleges that if an expert "deems" his report deficient, he is entitled to supplement (Arthrex Obj. at 5). But contrary to Arthrex's assertion that an expert has a "duty" to supplement whenever he feels like it, supplementation is not permitted under Rule 26 based on an expert's "inadequate or incomplete preparation." *Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002); *see also Sharpe v. U.S.*, 230 F.R.D. 452, 462 (E.D. Va. 2005) (denying supplementation to remedy experts' "incomplete or inadequate review"); *Coles v. Perry*, 217 F.R.D. 1, 3-4 (D. D.C. 2003) (striking late-filed report styled "supplemental opinion," noting that

---

<sup>2</sup> FED. R. CIV. P. 72 and Local Magistrate Rule 2(b) require that any objections to the Magistrate's ruling be made with 10 days of the Magistrate's Order. Arthrex only raised issues regarding Dr. Gitis' diameter measurement, the knot slippage strength test speed, and the pliability testing methodology (Arthrex Obj. at 3-4). Therefore, Arthrex waived any other objections.

“FED. R. CIV. P. 26(e) does not grant a license to supplement a previously filed expert report because a party wants to”); *Saint-Gobain Corp. v. Gemtron Corp.*, No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (W.D. Mich. May 9, 2006) (Ex. 22) (holding that expert could not supplement because expert simply wanted to add opinions). Further, Rule 26 only permits supplementation based on “information that was not available at the time” (*i.e.* during expert discovery). *DAG Enter., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 109-10 (D. D.C. 2005) (citation omitted); *Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (Ex. 22) (holding that expert could not supplement because information was available).

Not surprisingly, Arthrex’s position -- that experts are simply permitted to supplement their reports because they could have done a better job -- has been rejected because such a standard “would essentially allow for unlimited bolstering.” *Akeva L.L.C.*, 212 F.R.D. at 310; *see also Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (Ex. 22). Tellingly, Arthrex cites no case permitting it to supplement simply because Dr. Gitis could have done a better job.<sup>3</sup>

---

<sup>3</sup> Arthrex’s legal citations are no help to it here because the facts were completely different in those cases. *Schumacher v. Tyson Fresh Meats, Inc.*, No. CIV 02-1027, 2006 WL 47504, at \*6 (D. S.D. Jan. 5, 2006) (Arthrex Obj. at Ex. 3) (permitting rebuttal report to be served two weeks *before expert was deposed*); *Tracinda Corp. v. Daimlerchrysler AG*, 362 F. Supp. 2d 487, 506-08 (D. Del. 2005) (Arthrex Obj. at Ex. 4) (addressing issue of whether expert’s trial exhibits were admissible, not whether an expert was entitled to supplement); *Minebea Co., Ltd. v. Papst*, 231 F.R.D. 3, 7-8, 11 (D. D.C. 2005) (recognizing that Rule 26 “permits supplemental reports only for the *narrow purpose* of correcting inaccuracies or adding information that was *not available at the time of the initial report*,” and striking the “majority” of a supplemental expert report, and permitting only some small supplementation where there was no prejudice and where the expert was updating damages calculations) (emphasis supplied); *Wilson v. Sundstrand Corp.*, Nos. 99 C 6944, 6946, 2003 WL 22012673, at \*7-\*8 (N.D. Ill. Aug. 25, 2003) (Arthrex Obj. at Ex. 5) (permitting supplementation where opponent was on notice of proposed supplement before expert deposition began, supplementation was based on documents that expert did not have, but alerted opponent he would have before deposition began, supplementation was before expert deposition was completed and before rebuttal expert reports were due, and there was no unreasonable delay).



**B. Contrary to Arthrex's Assertions, An Expert is Not Permitted to Supplement Just Because It is More Than Thirty Days Before Trial**

Arthrex also reiterates another incorrect legal standard, alleging that an expert can supplement at will under FED. R. CIV. P. 26(a)(3), so long as it is thirty days before trial (Arthrex Obj. at 5). Where, as here, there is a Scheduling Order that sets forth the deadline for expert discovery, that order controls. *DAG Enter.*, 226 F.R.D. at 110 (holding that Rule 26 is “no safe harbor” for lack of diligence and failure to show good cause to ignore the deadline for expert discovery in Court’s scheduling order); *Sharpe*, 230 F.R.D. at 462-63 (denying motion to supplement more than thirty days before trial because expert discovery was closed per scheduling order). Permitting Arthrex to supplement at anytime more than thirty days before trial, as Arthrex suggests, would nullify the scheduling order, result in unlimited supplementation and depositions, and permit litigants to “hold back” until thirty days before trial.

**IV. Arthrex Has Not Proven That The Magistrate Committed Clear Error**

As Arthrex admits, it has the burden of proving that the Magistrate’s ruling was either “clearly erroneous or contrary to law” (Arthrex Obj. at 1). Arthrex has failed to satisfy that burden. Arthrex’s sole reason for asserting clear error is that the Magistrate’s Order was allegedly “based on her conclusion that defendants could not definitively prove that a virus was responsible for errors found in Dr. Gitis’ report” (*id.* at 4). But Arthrex cites to no record evidence to support its spin on the proceedings.

Trying to spin a story, Arthrex alleges that the “entire focus of DePuy Mitek’s motion was based on” the virus (*id.* at 3) and ignores, to its peril, the numerous other reasons for precluding supplementation that were before the Magistrate, any one of which could have formed a correct legal basis for the Order. For example, in the majority of Mitek’s reply paper and at the hearing, Mitek argued that there are numerous reasons in addition to the

unsubstantiated virus that preclude Arthrex from supplementing its expert reports at this late date (Ex. 21 at 5-11). Mitek argued that: (i) Arthrex failed to carry its Rule 26(e)(1) burden of providing credible evidence that there was a “typo” or a “reporting error;” (ii) Arthrex failed to show, as it is required to do under Rule 26(e)(1), that its proposed supplementation was based on information that was not available at the time of Dr. Gitis’ prior two reports and his deposition, and Arthrex did not delay in raising the issues; and (iii) Mitek would be prejudiced should Arthrex be allowed to supplement (Ex. 23 at 13-15; Ex. 21 at 9-10). Another proper legal basis for the Court’s Order was that the Magistrate could have been sanctioning Arthrex and Dr. Gitis for their entire conduct with respect to this supplementation issue. The Magistrate could have relied on any or all of these reasons in granting Mitek’s motion. Arthrex basically ignores these reasons, and therefore has failed to show clear error. Mitek addresses each of them below.

**A. Arthrex’s Argument that The Magistrate Erred By Attributing All Errors to The Mystery Virus Is Unsupported Rhetoric**

The Magistrate did not provide a detailed explanation for her ruling. Arthrex failed to request that the hearing be transcribed. Thus, Arthrex’s allegations that the Order was based solely on the virus are merely Arthrex’s unsupported, self-serving spin. There is simply nothing in the record to suggest that the Magistrate’s ruling is based *only* on the alleged computer “virus.”

**B. To the Extent the Magistrate’s Ruling Was Based on the Mystery “Virus” and Arthrex’s Conduct, Arthrex Has Not Shown Clear Error**

Arthrex tried to snow Mitek by alleging that its experts would redo their work based on a computer virus. Now, months after these virus allegations arose and after what Arthrex repeatedly describes as a “detailed investigation,” Arthrex has not provided a shred of proof of this virus, such as the name of the virus, what equipment it affected, or how it affected the equipment. In fact, Arthrex has not produced a single piece of paper related to this virus. After

forcing Mitek to bring a motion to prevent it from redoing expert discovery on the basis of this “virus,” Arthrex has now dropped the whole “virus” issue.

Arthrex should never have represented to Mitek or this Court that it was redoing expert reports based on an unsubstantiated virus. To the extent that the Magistrate ruled that Arthrex was not permitted to supplement as a sanction for Arthrex’s unsubstantiated virus allegations, Arthrex has not shown clear error.

**C. The Magistrate Did Not Commit Error Because Arthrex Failed to Satisfy Its Burden Under FED. R. CIV. P. 26(e)(1): Arthrex is Not Permitted To Supplement Because It Wishes Dr. Gitis Had Performed Better**

As a condition precedent to supplementing under FED. R. CIV. P. 26(e)(1), Arthrex had the burden of coming forward with evidence showing an inaccuracy based on “information that was not available at the time” of the report or during expert discovery, and not simply because it wishes Dr. Gitis had performed better. *See cases supra* cited at 7-8. Arthrex failed to satisfy this burden. Its alleged “inaccuracies” are directly contrary to Dr. Gitis’ sworn testimony, and they are just not believable.

**1. To the Extent the Magistrate’s Order Was Based On Arthrex Failing to Show That The Alleged Diameter “Typo” Was A “Typo,” Arthrex Has Not Shown Clear Error**

Suture diameter is relevant to Dr. Gitis’ purported suture “pliability” tests. Suture diameters cannot be measured accurately with a standard caliper -- a device that touches opposing points on a cylinder and measures diameter -- because sutures are very small in diameter and they are made from a relatively soft material (Ex. 14 at ¶22). But Dr. Gitis used a caliper and stated in his Report and at his deposition that he measured a diameter of 0.65 mm (Ex. 3 at 3 & Ex. 19 at 153:11-20). Although this was sloppy work, Dr. Gitis’ report accurately

details his diameter work. Therefore, because Dr. Gitis' report accurately describes his diameter measurements, there is no basis for supplementing.<sup>4</sup>

Arthrex now tries to cover up Dr. Gitis' sloppy work and make a substantive change by claiming that Dr. Gitis' reported suture diameter -- 0.65 mm -- was a typographical error, and that it should be 0.56 mm (Arthrex Obj. at 5). But this "typo" allegation is wholly unsupported and not believable based on the record evidence.

This "typo" excuse is not believable based on the timing of Dr. Gitis' allegations. If there was in fact a "typo," Dr. Gitis would have raised it much sooner, and certainly before Arthrex realized that its "virus" tactic would not work for the diameter problem. But Arthrex raised this new "diameter typo" excuse for the first time on August 28, 2006, in its opposition to Mitek's motion (D.I. 50 at 8, n.7). This was (i) over five months after Dr. Gitis served his expert report; (ii) over two months after Dr. Gitis' June 2006 supplemental report and deposition; and (iii) four months after Dr. Brookstein first criticized Dr. Gitis' "diameter" measurements (*compare* D.I. 50 *with* Exs. 3, 12, 19, and 24 at ¶49). It was also after Mitek showed in its motion papers that even if there had been a "virus," it provided no justification for redoing work – like diameter measurements – that could not possibly have anything whatsoever to do with a virus.

Not only does the timing of this "typo" excuse render it not credible, it is also not believable in light of Dr. Gitis' deposition testimony. If there had been a typographical error, Dr. Gitis would have recognized it at his deposition. Rather, he *repeatedly* testified that he personally measured the suture to be 0.65 mm. in diameter.

---

<sup>4</sup> *Sharpe*, 230 F.R.D. at 462 (denying supplementation where party sought to correct experts' faulty opinions); *DAG Enters.*, 226 F.R.D. at 109-110 (holding that supplementation does not permit a party to simply substitute an old report for a new one); *Akeva*, 212 F.R.D. at 310 (holding that Rule 26(e)(1) "does not cover failures of omission because the expert did an inadequate or incomplete preparation").

- Q. Okay. And the diameter you say is **.65 millimeters**.  
 A. Measured this by caliper.  
 Q. Did you measure the diameters?  
 A. Yes.  
 Q. Of each sample?  
 A. Yes.  
 Q. Every sample?  
 A. Not every sample, but we measured it at least 10, 12 times, yeah.  
 Q. And you always got .65 millimeters?  
 A. Pardon me?  
 Q. And you always got **.65 millimeters**?  
 A. **Yes**.  
 Q. For each sample?  
 A. **Yes**.  
 Q. So the coated and uncoated, did you measure the diameter?  
 A. Yes.  
 Q. And they were the same?  
 A. Yes.  
 Q. No difference?  
 A. No difference as measured with a caliper.
- Q. And you calculated an average diameter?  
 A. ***This is what we planned to do, but we didn't have to do it because many measurements that we did produced the same result, .65.***
- Q. Okay, if you go to -- one column says non-absorbable and synthetic absorbable sutures, and there's a number 2. Do you see that?  
 A. Yes.  
**Q. And it has diameter limits of .5000 to .599 for that. Do you see that?**  
**A. Yes.**  
**Q. And the diameter you used of .655 [sic 0.65] is above those diameter limits, right?**  
**A. Yes.**

(Ex. 19 at 153:11-154:9; 165:1-4; and 172:23-173:7) (emphasis added). Thus, this belated “typo” excuse is nothing more than an after-the-fact concocted reason for trying to cover up Dr. Gitis’ sloppy work.

Also, Dr. Gitis’ “typo” excuse was not supported by any credible evidence that was before the Magistrate. The only evidence of a “typo” that Arthrex submitted was Dr. Gitis’ carefully-worded affidavit. Tellingly, Dr. Gitis merely states that “there *appears* to be a

typographical error in the reporting of the suture diameter” (Ex. 20 at ¶34). But “appears” to be a typo is not sufficient evidence to show that a typo was actually made, particularly in light of Dr. Gitis’ sworn testimony to the contrary.

Finally, Dr. Gitis’ “typo” excuse is not believable because Dr. Gitis testified that he did not record the diameter measurements when he made them (Ex. 19 at 174:7-10). Thus, he has no documents that would show that this was a typographical error. As he lacks any contemporaneous documentation, it is just not believable that he suddenly realized months later that there was a “typo.” Further, Dr. Gitis’ inexplicable failure to keep written records of his measurements should not now provide him with cover for redoing sloppy work.

Dr. Gitis’ report accurately shows Dr. Gitis’ work. He used an incorrect technique for measuring suture diameter and came up with bad results. Thus, to the extent that the Magistrate’s order was based on Arthrex’s failure to satisfy its burden of proving an inaccuracy, as is required as a condition precedent to supplementing under FED. R. CIV. P. 26(e)(1), Arthrex has not shown clear error.

**2. To the Extent the Magistrate’s Order Was Based On Arthrex Failing to Show That The Alleged Pliability Test Had A “Reporting Error,” Arthrex Has Not Shown Clear Error**

Dr. Gitis purportedly performed a “pliability” test to determine whether FiberWire’s coating affected FiberWire’s pliability. But Dr. Gitis did the wrong test; he performed a tension test, not a pliability test. A tension test can only be used as a measure of pliability if certain assumptions are true. But these assumptions do not hold for FiberWire (Ex. 24 at ¶¶45-52; Ex. 13 at ¶¶11-17). One of the many mistakes that Dr. Gitis made was that he reported and testified under oath that the purported pliability test was performed by *increasing the load*, rather than the *extension*, at a constant rate. Accordingly, because of Dr. Gitis’ many mistakes, Dr. Mukherjee,

Arthrex's other technical expert, had to admit on cross-examination that Dr. Gitis did not measure pliability:

- Q. Did you approve the pliability tests that Dr. Gitis did before he did it?
- A. He's the authority. He decided on it and -- and we just did the -- *we didn't measure pliability, all right?* That is the extent of conversation I had. He decided the procedure and the technique.

(Ex. 18 at 425:2-9) (emphasis added) (objection omitted). Thus, at the end of expert discovery, Arthrex was faced with a conundrum; its experts carried out and relied on the wrong test.

Arthrex tried to work its way out of this predicament by alleging "virus" (Ex. 15). But, as Mitek pointed out in its motion papers, even if there were a virus, that is no reason for changing testing methodology because the choice of the wrong test was human error, not a result of any virus (Exs. 21 at 5-9 & 23 at 9-11).

Arthrex and Dr. Gitis then tried to justify report supplementation by alleging a "reporting" error (D.I. 50 at 8, n.7). But this excuse is just not believable based on Dr. Gitis' sworn testimony. Dr. Gitis testified that he performed the so-called "pliability" test by uniformly increasing the load (Ex. 3 at 3), that he determined from his own research that the test should be carried out using "*a constant rate of loading*," that he instructed his employees to conduct the test at "*a constant rate of loading*," and that he, himself, observed the tests:

- Q. Were you present for at least some of the actual testing of the pliability samples for pliability?
- A. Yes, I was present in at least some of each and every test, each type of test.
- Q. And how is that controlled by the machine?
- A. It is the same servo-control as we discussed before.
- Q. It's measuring the *force applied*?
- A. Yes.
- Q. And it's programmed into it to *increase it*?
- A. Yes.

- Q. Who actually wrote this report?
- A. I did.
- Q. You did? So you put the *0.33 kilogram per second uniform increase in*?
- A. Yes.
- Q. Where did you get that from?
- A. From my engineers. They gave me the number.
- Q. You got that from them?
- A. Yeah.
- Q. Did you program yourself, did you put into the machine the *rate at which the load should go up*?
- A. No, I did not.
- Q. Do you have any documents where you specified the parameters for the test that should be inputted into the machine?
- A. Yes. If it's not provided in the Excel files -- what documents do you mean?
- Q. Like, for example, if you wrote, either typed up or handwritten, said to your assistant, said, okay, the pliability tests, here is how want you to run it, 50 centimeter gauge length, *uniform increase of load at this rate*, preload of this. Did you make some kind of document?
- A. No.
- Q. You just orally told him?
- A. Yes.
- Q. Okay. And do you know how you arrived at the *.33 kilogram per second*?
- A. It was from some -- again, from the same references. From one of the references cited.
- Q. Either the --
- A. Rodeheaver or --
- Q. Bizwada patent?
- A. Yeah.

(Ex. 19 at 84:16-20; 152:1-9; and 175:1-176:11, emphasis added).

Further, Dr. Gitis' "reporting error" excuse is just not believable based on the timing of his excuse. Like his "diameter" excuse, Arthrex raised this new "reporting" excuse for the first time on August 28, 2006, in its opposition to Mitek's motion (D.I. 50 at 8, n.7), months after Dr. Gitis served his expert report and after he was deposed. Further, the only evidence Arthrex submitted to the Magistrate to show a "reporting" error was a conclusory statement from Dr. Gitis' affidavit with no supporting proof. Thus, to the extent the Magistrate based the Order on the fact that Arthrex did not satisfy its burden of establishing that Dr. Gitis' pliability test was



done at a constant extension rate, Arthrex has not shown clear error. Further, supplementation is not permitted just because Arthrex wishes its expert did a better job. *See cases supra* cited at 7.

### **3. The “Typo” in the Reported Test Speed Is A Substantive Change That Was Not Before The Magistrate**

Arthrex now asserts -- for the first time -- that it wants to change Dr. Gitis’ report with respect to how his knot slippage strength tests were conducted. Dr. Gitis asserts that these tests were performed at a speed of 0.134 mm/sec instead of 1 mm/sec, as Dr. Gitis stated in his Report and at his deposition (Ex 3 at 5; Ex. 19 at 201:24-202:15). According to Arthrex, this error was a “typo,” but Arthrex provides no evidence other than conclusory statements here in support of this allegation. Further, Arthrex never mentioned this “typo” during the parties’ briefing and arguments. Thus, Arthrex can hardly attribute clear error to the Magistrate when Arthrex failed to even raise the issue. Further, Arthrex waived this issue by not raising it before the Magistrate.

### **D. To the Extent the Magistrate’s Ruling Was Based on Arthrex’s Untimeliness, Arthrex Has Not Shown Clear Error**

A third independent reason why the Magistrate did not commit clear error was that Arthrex failed to carry its burden of showing that the alleged supplementation is based on information that was unavailable to Dr. Gitis when he prepared his report, when he supplemented his report, and at his deposition, and that Arthrex did not delay in raising these issues.<sup>5</sup> If there were in fact any “typos,” the relevant information was certainly available to Dr. Gitis when he generated his reports in March and June 2006 and at his June 2006 deposition because all of the

---

<sup>5</sup> *Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (Ex. 22) (holding that expert could not supplement where party trying to supplement could not show that the new information was unknown to it); *Keener v. U.S.*, 181 F.R.D. 639, 640-642 (D. Mont. 1998) (holding that expert could not make untimely “supplemental” opinions); *Schweizer v. DEKALB Swine Breeders, Inc.* 954 F. Supp. 1495, 1510 (D. Kan. 1997) (excluding supplemental report of expert containing new opinions when there was no reason the opinions could not have been expressed in the expert's original report).

information originates with him, not Mitek. Further, Dr. Gitis testified at deposition that he had checked his report and the data (Ex. 19 at 85:12-18; 197:9-24).

Arthrex has repeatedly failed to address its delay. This Court should not do so, and this is reason enough for denying Arthrex's motion. Arthrex cannot show clear error.

**E. To the Extent the Magistrate's Ruling Was Based on Prejudice to Mitek, Arthrex Has Failed to Show Clear Error**

Mitek pointed out in its briefs and at oral argument that permitting Dr. Gitis to supplement would substantially prejudice Mitek. To the extent that the Magistrate's ruling was based on that prejudice, Arthrex has not even addressed it, much less shown clear error. Having failed to object on this basis, Arthrex has waived any objection.

Arthrex tries to minimize the prejudice by Dr. Gitis' proposed supplementation by using words like "typos" and "reporting errors." But make no mistake, these are substantive changes, otherwise Arthrex would not be going to such lengths to change Dr. Gitis' testimony. Basically, if Arthrex is permitted to supplement, Mitek will be prejudiced because there will be a second round of expensive expert discovery. Mitek will have to redepose Dr. Gitis and investigate the veracity of his recent claims. This would include forensic inspection and analysis of his laboratory equipment to determine whether they support his recent allegations that his pliability test was run differently than he reported, investigation by Mitek's experts, Dr. Brookstein and/or Dr. Hermes, into the data and analysis of Dr. Gitis' new report, and possible depositions of Dr. Gitis' lab assistants who helped him with these tests. Mitek's experts, Dr. Brookstein and/or Dr. Hermes, would have to submit new reports.<sup>6</sup> Arthrex would likely opt to depose Dr. Brookstein and/or Dr. Hermes. All of this will involve expert fees and extensive attorney fees. Arthrex

---

<sup>6</sup> Mitek asked Dr. Brookstein to perform certain work based on the complete ridiculousness of Dr. Gitis' work. If Dr. Gitis is permitted to supplement and basically redo his opinions, then Mitek may ask for additional opinions.

pretends that there will be minimal expense because Mitek will just accept these “typo” excuses as truth. But, just as Mitek will not accept an unsubstantiated virus claim, Mitek will not accept “typo” excuses and will fully investigate them.

Not only will this prejudice Mitek, but it will prejudice the Court as well. Dispositive motions have been briefed and heard. It is hard to believe that the outcome of further expert reports and discovery will not be relevant to the pending motions. Certainly, if evidence is developed that is beneficial to Mitek, Mitek should be permitted to submit it to the Court.

Before the Magistrate, Arthrex had erroneously argued that prejudice to Mitek was irrelevant to the supplementation issue (D.I. 50 at 15). But Arthrex is wrong. Courts routinely consider the issue of prejudice because a party seeking supplementation of this nature is basically asking to reopen expert discovery and to burden its opponent. *Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (Ex. 22) (noting prejudice that will result from supplementation); *DAG Enters.*, 226 F.R.D. at 110 (discussing prejudice); *Sharpe*, 230 F.R.D. at 462 (declining motion to supplement because opponent should not be prejudiced with supplementation while it is completing discovery and preparing for trial in the confines of the Court’s scheduling order).

**F. Mitek’s Expert’s Amended Supplemental Expert Report Was Before His Deposition And Provides No Refuge For Arthrex**

Arthrex argues that because Dr. Brookstein, a Mitek expert, amended his expert report, Arthrex can supplement its expert reports whenever it wants. But the two situations are completely different. Unlike Dr. Gitis, Dr. Brookstein amended his expert report to correct legitimate and apparent errors<sup>7</sup> during expert discovery, within about ten days of submitting his report and before his deposition. (*compare* Exs. 14, 13, and 25).

---

<sup>7</sup> Dr. Brookstein supplemented his report to correct an erroneous reference to the same samples as both “treated” and “untreated” (a clear typographical error) and to list two additional documents he had consulted.

**V. If Arthrex Is Permitted to Supplement, It Should Pay Mitek's Costs Associated with Redoing Expert Discovery**

Arthrex should not be permitted to turn back time and redo expert discovery on issues to its liking. But if it is permitted to do so, Mitek should not bear additional legal costs because of Arthrex's mistakes. Thus, if Arthrex is permitted to supplement, Mitek requests that the Court order Arthrex to pay all fees and costs associated with any and all additional expert reports and discovery, and supplemental briefing.

**VI. Arthrex Should Not Be Permitted To Defy the Magistrate's Order**

Playing word games, Arthrex now relabels many of Dr. Gitis' proposed supplements – which it did not raise here – as so-called “responsive” opinions, and asserts that it will simply submit them at trial despite the Order because they allegedly need not be in an expert report (Arthrex Obj. at 4, n.2). Arthrex is just wrong. FED. R. CIV. P. 26(a)(2)(B) requires that all of Dr. Gitis' opinions and the basis for them be in his Expert Report. Therefore, Arthrex should not be permitted to defy the Magistrate's Order by restyling Dr. Gitis' proposed supplementation as mere “response.”

**VII. Conclusion**

Magistrate Bowler's Order precluding Arthrex from supplementing its expert reports should be adopted because Arthrex has not cited any evidence showing clear error. Arthrex should not be permitted to make substantive changes to expert reports that were due over seven months ago, after the close of expert discovery, and after summary judgment motions have been filed and argued.

Dated: November 20, 2006

DEPUY MITEK, INC.,  
By its attorneys,  
/s/ Erich M. Falke  
Dianne B. Elderkin  
Lynn A. Malinoski  
Michael J. Bonella

Erich M. Falke  
WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
(215) 568-3100

Daniel J. Gleason (BBO #194900)  
Heather Repicky (BBO #663347)  
Nutter McClennen & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA. 02210-2604

**CERTIFICATE OF SERVICE**

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

**DePuy Mitek's Response To Defendants' Objections To Magistrate's Order  
Granting DePuy Mitek, Inc.'s Motion To Preclude Arthrex, Inc. And Pearsalls Ltd.  
From Supplementing Their Expert Reports And Depositions**

was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber  
Dickstein Shapiro  
1825 Eye Street, NW  
Washington, DC 2006  
[saberc@dicksteinshapiro.com](mailto:saberc@dicksteinshapiro.com)

Raymond P. Ausrotas  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109  
[rausrotas@toddweld.com](mailto:rausrotas@toddweld.com)

Dated: November 20, 2006

/s/ Erich M. Falke

Erich M. Falke

# **EXHIBIT 1**



US005314446A

**United States Patent** [19]

Hunter et al.

[11] **Patent Number:** 5,314,446[45] **Date of Patent:** May 24, 1994[54] **STERILIZED HETEROGENEOUS BRAIDS**[75] **Inventors:** Alastair W. Hunter, Bridgewater;  
Arthur Taylor, Jr., Plainfield, both of  
N.J.; Mark Steckel, Maineville, Ohio[73] **Assignee:** Ethicon, Inc., Somerville, N.J.[21] **Appl. No.:** 838,511[22] **Filed:** Feb. 19, 1992[51] **Int. Cl.<sup>5</sup>** ..... D04C 1/00[52] **U.S. Cl.** ..... 606/231; 606/228;  
87/7; 87/9; 428/370[58] **Field of Search** ..... 606/228, 230, 231;  
87/7, 8, 9; 428/225[56] **References Cited****U.S. PATENT DOCUMENTS**

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

**FOREIGN PATENT DOCUMENTS**

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

*Primary Examiner*—George F. Lesmes*Assistant Examiner*—Chris Raimund*Attorney, Agent, or Firm*—Hal Brent Woodrow

[57]

**ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

**12 Claims, 3 Drawing Sheets**



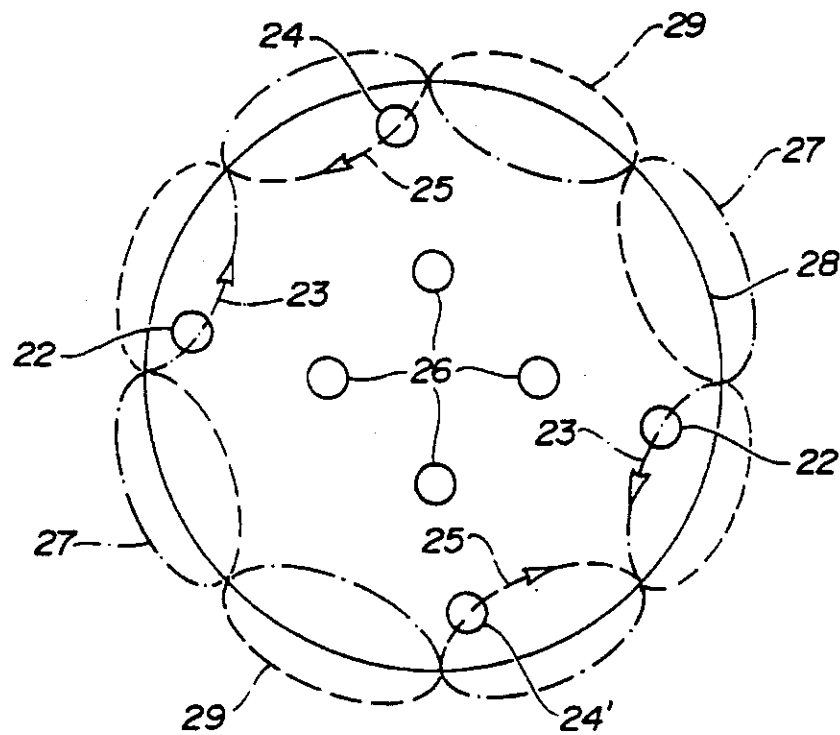
U.S. Patent

May 24, 1994

Sheet 1 of 3

5,314,446

FIG-1



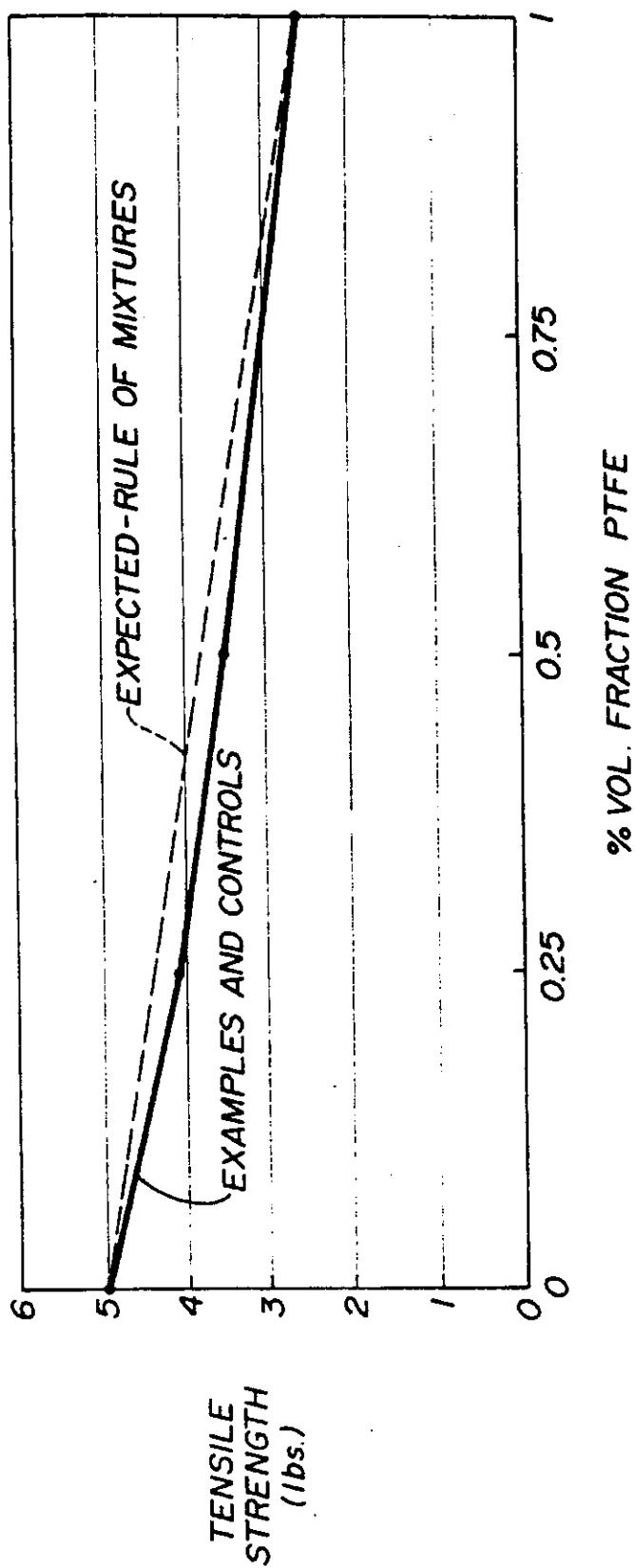
U.S. Patent

May 24, 1994

Sheet 2 of 3

5,314,446

FIG-2



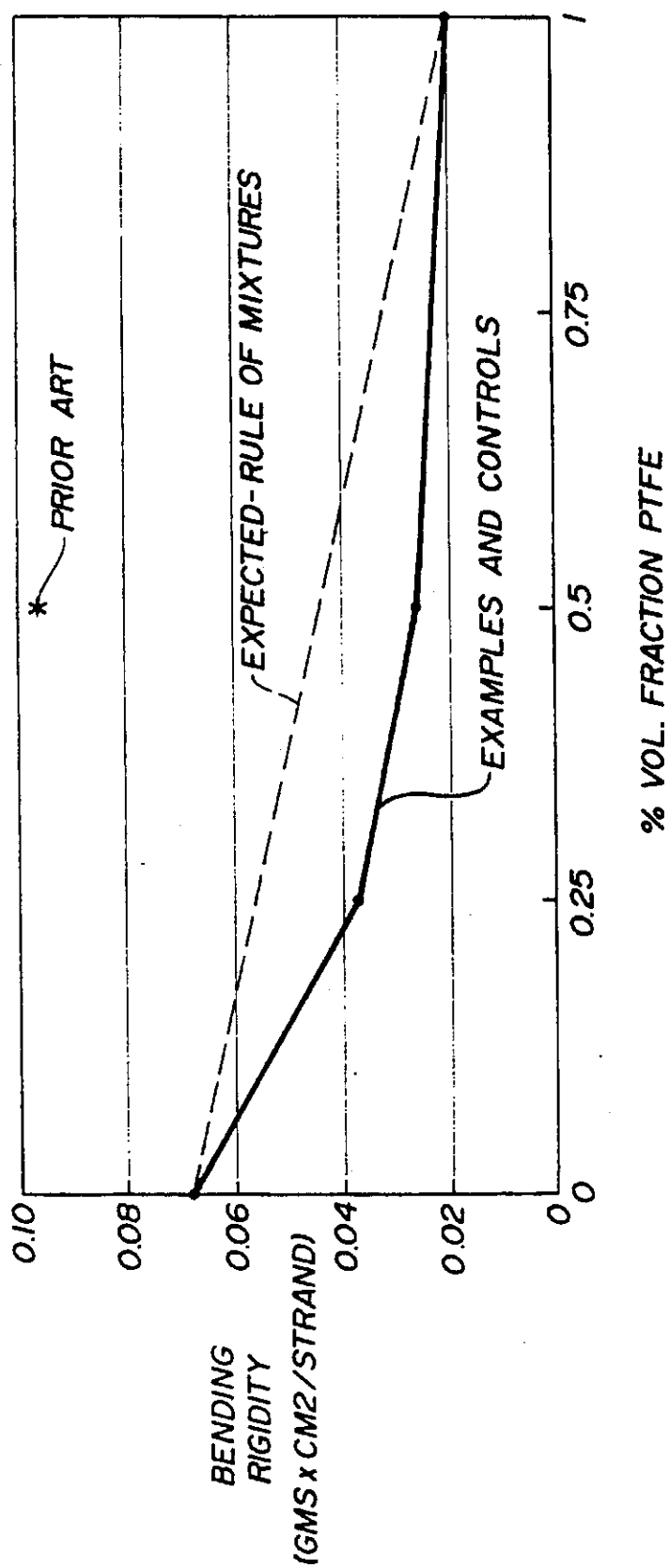
U.S. Patent

May 24, 1994

Sheet 3 of 3

5,314,446

FIG-3



1

5,314,446

2

## STERILIZED HETEROGENEOUS BRAIDS

### BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent  $\epsilon$ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricious polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

### SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

5,314,446

3

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

### DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

4

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

5

5,314,446

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

6

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

#### EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.



7

## CONTROL I

**FIBER MATERIALS:** An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

**PROCESSING:** The yarns are wound on braider

5,314,446

8

**PROCESSING:** Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm <sup>2</sup> )	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	3
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

## CONTROL II

**FIBER MATERIALS:** An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

**PROCESSING:** The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

## EXAMPLE I

**FIBER MATERIALS:** An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

**PROCESSING:** Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

## EXAMPLE II

**FIBER MATERIALS:** Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

**PROCESSING:** Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

## PRIOR ART I

**FIBER MATERIALS:** Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f a) (P_a) + (V_f b) (P_b)$$

where  $P_c$  is a composite property (such as tensile strength or modulus),  $P_a$  and  $P_b$  are the properties of the components a and b, and  $V_f a$  and  $V_f b$  are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

5,314,446

9

- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
  - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
  - c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

10

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

\* \* \* \* \*

25

30

35

40

45

50

55

60

65



# **EXHIBIT 2**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.,</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom,</b>	)	
	)	
<b>Defendants.</b>	)	

**Expert Report of Dr. David Brookstein**

**I. Background Information**

**A. Teaching Experience**

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

**B. Work Experience**

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

**C. Publications**

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites," TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

#### **D. Patents**

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

**E. Education**

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV. Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of \$300/hour.

## **II. Summary of Opinions**

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the '446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term "FiberWire™ suture products" to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term "TigerWire™ suture products" to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex's FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the '446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the '446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

### **III. Materials Considered in Forming My Opinions**

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex's Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grieff, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.



23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

#### **IV. Legal Framework of My Opinions**

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

##### **A. Direct Infringement**

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is “literal” when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

## **V. Direct Infringement**

### **A. Claim Construction**

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the ‘446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“direct intertwining contact” –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

## **B. Literal Infringement**

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

### **1. Arthrex's FiberWire™ and TigerWire™ Suture Products**

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™<sup>1</sup> product that “is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture” (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with “Spectra” and “Dyneema” ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies’ ultra high molecular weight polyethylene.

32. Arthrex’s FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™<sup>2</sup> product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

---

<sup>1</sup> Because TigerTail™ includes FiberWire™, TigerTail™ infringes the ‘446 patent for the same reasons that FiberWire™ infringes.

<sup>2</sup> Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the ‘446 patent for the same reasons that FiberWire™ does.

**2. Arthrex's FiberWire™ and TigerWire™ Suture Products  
Literally Infringe Claim 1**

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products<sup>3</sup> literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

<b>Claim 1 of the '446 Patent</b>	<b>FiberWire™ and TigerWire™ Suture Products</b>
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET). <sup>4</sup> The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

<sup>3</sup> I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

- <sup>4</sup> Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
- A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Tab D at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.<sup>5</sup>

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

---

<sup>5</sup> My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are “tipped.” I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex’s position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the ‘446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex’s TigerWire™ is substantially identical to Arthrex’s FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.



Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.<sup>6</sup> I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

---

<sup>6</sup> Q. Sure. Sure. Is the braid in any Arthrex TigerWire™ different than the braid used in Arthrex's No. 2 FiberWire™?

A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

**3. Arthrex's FiberWire™ and TigerWire™ Needle Products  
Literally Infringe Claim 2**

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products<sup>7</sup> literally have all of the limitations of claim 2.

<b>Claim 2</b>	<b>Arthrex's FiberWire™ and TigerWire™ needle products</b>
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

**4. Arthrex's FiberWire™ and TigerWire™ Suture Products  
Literally Infringe Claim 8**

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products<sup>8</sup> literally infringe claim 8 of the '446 for the following reasons:

<b>Literal FiberWire™ Structure</b>	<b>Claim 8</b>
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

<sup>7</sup> Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

<sup>8</sup> I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

(DMI Ex. 318).
----------------

**5. Arthrex's FiberWire™ and TigerWire™ Suture Products  
Literally Infringe Claim 9**

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products<sup>9</sup> literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

<b>Claim 9</b>	<b>Arthrex's FiberWire™ and TigerWire™ Products</b>
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

<sup>9</sup> Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-75SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

**6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12**

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products<sup>10</sup> literally have all of the limitations of claim 12.

<b>Claim 12</b>	<b>Arthrex's FiberWire™ and TigerWire™ Needle Products</b>
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

**C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents**

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

---

<sup>10</sup> Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the “function/way/result” test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the “function” of the first fiber-forming material is the same as the function of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>Function of Limitation Under the Doctrine of Equivalents</b>	<b>Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products</b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the “function” of the first fiber-forming material is supported by the ‘446 Patent. The ‘446 Patent explains that the first fiber forming material is “dissimilar” to the second fiber and the braid of dissimilar yarns provides “outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Tab D at 2:50-52; 3:43-48). Further, the ‘446 Patent explains that it is possible to “tailor the physical” properties by “varying the type and proportion of each of the dissimilar fiber forming materials used” (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the “way” of the first fiber-forming material is the same as the “way” of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>“Way” of Limitation Under the Doctrine of Equivalents</b>	<b>Way UHMWPE performs its Function in FiberWire™ and TigerWire™</b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The “way” is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the “way” of the “first fiber-forming” element is supported by the ‘446 Patent. The ‘446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the ‘446 Patent states in the “Summary of the Invention” section that the “the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction” and that the at least one yarn from the first set is in “direct

intertwining contact” with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The ‘446 Patent further explains that the heterogeneous braid properties are due to the “mechanical interlocking or weaving of the individual yarns” (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct “intertwining” contact of dissimilar yarns (December 2, 1992 Office Action at 2, *emphasis original*).

59. Further, the ‘446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The ‘446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these “preferred embodiments,” and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products have the same “way” as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex’s FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

<b>Claims 1, 2, 8, 9, and 12 Limitation</b>	<b>"Result" of Limitation Under the Doctrine of Equivalents</b>	<b>Result of UHMWPE in FiberWire™</b>
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Tab D at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when



the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

Q What did you understand Mr. Grafton to mean when he said:

"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".

What did you understand that to mean?

A Yes, that he wanted a braid which was more -- not so stiff.

Q As the 100% ultra high molecular weight polyethylene?

A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?

A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

**VI. Opinions Regarding Contributory Infringement**

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex's FiberWire™ and TigerWire™ suture products. (Arthrex's Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the '446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The '446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the '446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls' Answers to Mitek's First Set of Interrogatories).

## VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been “enthusiastically endorse[d]” for “its feel.” (DMI Ex. 7 at 2). FiberWire™’s and TigerWire™’s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™’s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™’s and TigerWire™’s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the ‘446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the ‘446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex’s and Pearsalls’ development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

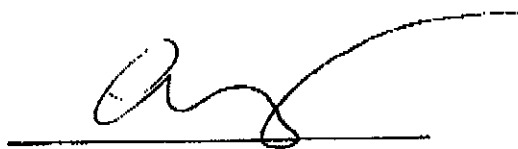
UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that “that FiberWire™ is a “Braided Polyblend Suture” that it is “revolutionizing Orthopaedic Surgery” (DMI Ex. 7 at 1). I also note that Arthrex’s claims that its FiberWire™ heterogeneous braid has superior properties is supported by “multiple scientific publications” (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the ‘446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™’s heterogeneous braid is superior to Ethibond’s homogeneous braid. For example, Arthrex claims that the FiberWire™ is “twice as strong” as “polyester suture” (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that “FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile” (DMI Ex. 13; *emphasis added*). Arthrex claims that its studies show that FiberWire™ has better knot strength than “Ethibond Excel braided polyester suture” (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™’s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex’s FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.  
Fellow-American Society of Mechanical Engineers

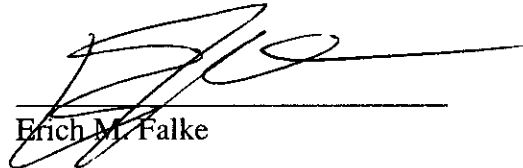
### **CERTIFICATE OF SERVICE**

I certify that the foregoing Expert Report of Dr. David Brookstein was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 3, 2006 on the following:

Charles W. Saber  
Dickstein, Shapiro, Morin & Oshinsky, LLP  
2101 L. Street, NW  
Washington, DC 20037-1526.

Christopher Weld, Jr.  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109

Dated: March 3, 2006

  
\_\_\_\_\_  
Erich M. Falke

# **EXHIBIT 3 – Part 1 of 7**



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

"Confidential-Non-Patent-  
Prosecution Counsel Only"

March 23, 2006

**Comparative Suture Testing****1. Introduction**

Center for Tribology, Inc., abbreviated CETR, is a privately held California corporation, located in the heart of Silicon Valley in the city of Campbell, county of Santa Clara. It was founded by Dr. Norm Gitis in November 1993 and incorporated in California in October 1994. Its main charter has been helping major corporations and universities all over the world in research, development and failure analysis of materials, coatings and lubricants for the computer peripherals (20% of revenues), semiconductor (20% of revenues), biomedical (15% of revenues) and other industries (20% of revenues), as well as for fundamental academic studies (25% of revenues). A list of its customers is attached in Appendix 1.

CETR is a multi-million-dollars corporation with two lines of business, design & sales of mechanical & tribology test equipment (90% of revenues) and testing & consulting services on mechanical & tribological properties of materials and devices (10% of revenues).

CETR is one of the largest and leading producers of mechanical and tribology testers in the world. In particular, it has supplied them to leading domestic suture manufacturers, such as Ethicon, Inc. of Johnson & Johnson and United States Surgical of Tyco Healthcare, as well as such well-known corporations as Gillette, Guidant, Medtronic, Schick, Procter & Gamble, Unilever, etc.

Dr. Norm Gitis, President of CETR, is a well-known expert on tribology testing with 30 years of experience in friction, wear and fatigue testing of materials and devices. His resume is attached in Appendices 2a – 2c.

CETR has successfully provided highest quality laboratory test data in several lawsuits, including most recently between Alaska Airlines, Boeing, and families of victims of the Alaska flight 261 (related to the reliability of a jack-screw/nut assembly on Boeing airplanes and a plane crash in 2000), between American Airlines, Sabre Travel Network and Western Digital (related to the reliability of computer disk drives used for travel reservations), and between Boston Scientific and US Justice Department (related to the quality of implantable cardiovascular stents). It has been charging \$ 2,500 per day or \$ 10,000 per week for its regular lab testing services and double prices for priority urgent services.

Dr. Gitis has successfully testified in several depositions, most recently in a lawsuit between Seagate Technology and Cornice, Inc. related to the intellectual property on the mechanical design of portable magnetic disk drives. He has also given successful testimonies at several trials, most recently in lawsuits between Swiss Air, Interactive Flight Technology, Avnet and other parties (related to the reliability of computerized on-demand in-flight video system and a crash of Swiss flight 111) in the court of Arizona and between Iomega and Nomai (related to the reliability of Zip high-density floppy-drives) in the Higher Court of





## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

United Kingdom, courts of Amsterdam, Dusseldorf, etc. He has been charging \$ 350 per hour plus trip expenses for his consulting and expert witnessing services.

### **2. Project Goal**

At the end of February 2006 CETR was requested by a law firm of Dickstein, Shapiro, Morin & Oshinsky, LLP (located at 2101 L Street NW, Washington, DC 20037) and its technical expert Dr. Debi Mukherjee to perform comparative mechanical and tribological testing of two types of FiberWire surgical sutures, coated and uncoated.

They requested the following parameters be tested: i) pliability/bendability, ii) knot tie-down/run-down, iii) knot security, iv) chatter, v) coefficient of friction, vi) tissue drag, vii) microscopy examination.

We have been told that this project is related to a patent infringement lawsuit between DePuy Mitek, a Johnson & Johnson company and Arthrex, the latter being the client of this law firm. Any details of the lawsuit have been neither requested by CETR nor provided to CETR.

### **3. Suture Samples**

In the beginning of March 2006 CETR received via FedEx two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated. Each spool contained approximately 20 m of suture. Two CETR employees Dr. Norm Gitis and Mr. Michael Vinogradov examined the spools of sutures and found them to be apparently brand new.

Upon agreement with the law firm and Dr. Mukherjee, before conducting any tests, we sent both the spools of sutures for ETO sterilization to a reputable sterilization lab Sterile Systems, Division of Medtronic Inc. (located at 520 Watson S.W., Grand Rapids, MI 49504). The same Mr. Michael Vinogradov handled the sutures before the shipment and after receiving them back. Both shipments to and from Sterile Systems were performed via FedEx.

Upon receiving back the sterilized sutures, we handled them only and always with clean-room gloves. We cut about 3 m of each of the coated and uncoated sutures and shipped by FedEx to a surgeon expert, as requested by the law firm. The rest of the spools were utilized in our tests described below.

### **4. Set Of Test Procedures**

Based on the CETR experience with its suture-tester customers Ethicon (New Jersey) and US Surgical (Connecticut), its general expertise in mechanical & tribology testing and familiarity with the relevant literature, as well as on the suggestions of the law firm, CETR has proposed a suit of test procedures for the requested tests, that was approved by the law firm's technical expert Dr. Mukherjee and then performed by CETR in mid-March, 2006.

### **5. Pliability Tests**

The experimental procedure, based on the published work of Rodeheaver et al. [1], was as follows.



# CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

Suture of 50 mm in length and 0.65 mm in diameter was clamped between the force sensor and the lower specimen holder as shown in fig. 1. The suture was preloaded with a tension of 0.5 Kg (5 N). Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kg/sec. Force and elongation data were continuously monitored and recorded. The strain in the suture was calculated as the ratio of elongation to the initial length of 50 mm. The force-strain plots like the one shown in fig. 2 were made and their slopes were measured. Modulus of elasticity (E) was then calculated by dividing the slope with the cross-sectional area of the suture. Area moment of inertia (I) was calculated assuming a circular cross-sectional area. Stiffness was then calculated as a product of the modulus of elasticity and the area moment of inertia of the suture:

$$K = E \cdot I$$

where

K – Stiffness,

E - Modulus of elasticity - Slope of the force-strain graph / cross-sectional area of the suture

I - Area moment of inertia -  $\frac{\pi * D^4}{64}$  where D - diameter of the suture (0.65 mm)

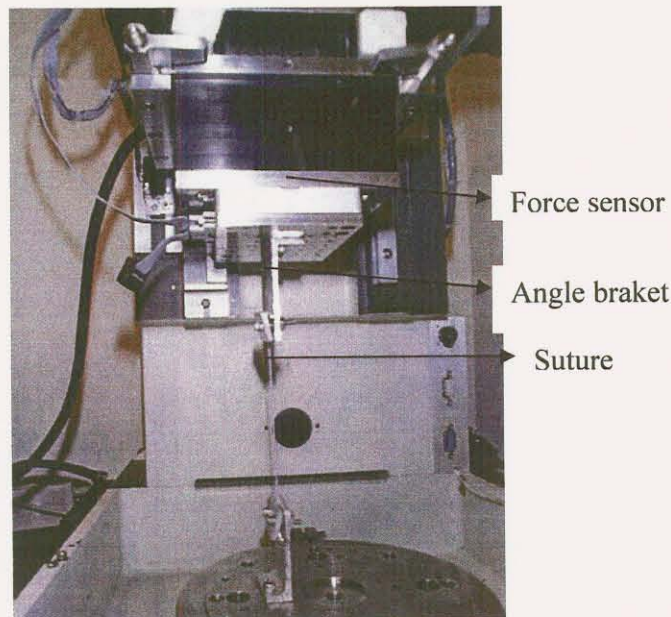


Figure 1. Test set up for pliability testing





# CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

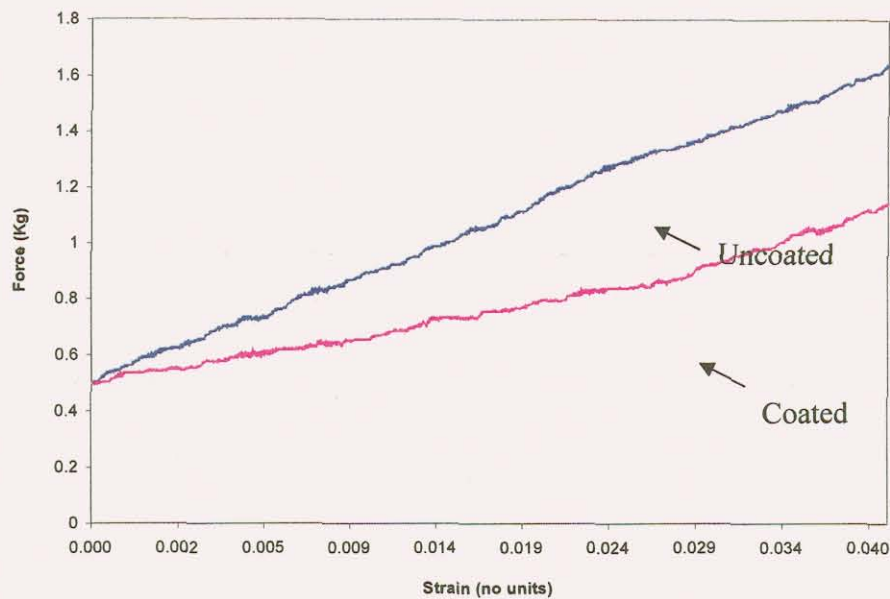


Figure 2. Typical force-strain data for coated and uncoated sutures during pliability tests

The stiffness values as calculated in the above described procedure are summarized in the Table 1.

Table 1. Pliability test data

Exp #	Stiffness (*E10-7 kg x m <sup>2</sup> )	
	Coated Suture	Uncoated Suture
1	6.51	10.07
2	7.53	9.73
3	5.98	11.3
4	6.44	11.3
5	4.95	8.29
6	5.67	8.00
7	5.98	9.61
8	5.41	10.6
Average	6.06 ± 1.29	9.93 ± 1.66

The stiffness of the coated sutures was found to be lower than that of the uncoated ones. This suggests that the coated sutures have higher pliability and thus facilitate better handling during surgical use. The test data corresponds well to the data reported by Rodeheaver et al [1].



## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

### 6. Knot Slippage Strength Tests

The knot slippage strength tests were conducted to evaluate the knot security offered by each suture. The experimental procedure was carried out based on previous works in the literature [2, 3]. A loop of the suture was formed by tying a 'square knot' as shown in fig 3 [4] around a cylinder of 2.5 cm diameter. The loop thus formed was slipped off the cylinder and soaked in 0.9% weight/volume sodium chloride for 1 minute to closely represent the real environment. The soaked loop was then placed around 2 parallel brass rods of 5 mm diameter, which were mounted onto the UMT-2 machine as shown in fig. 4. A pre-load of 1 N was applied to the loop. The parallel rods were then pulled apart at a constant velocity of 1 mm/sec. The force was continuously monitored and recorded during the experiment. The force when the knot starts slipping was noted as the knot slippage force. The rods continued to be pulled apart until either the knot got untied or a slippage of 3 mm occurred. The force at that instant gives the knot failure force.



Figure. 3 'Square knot' used for the knot slippage strength tests

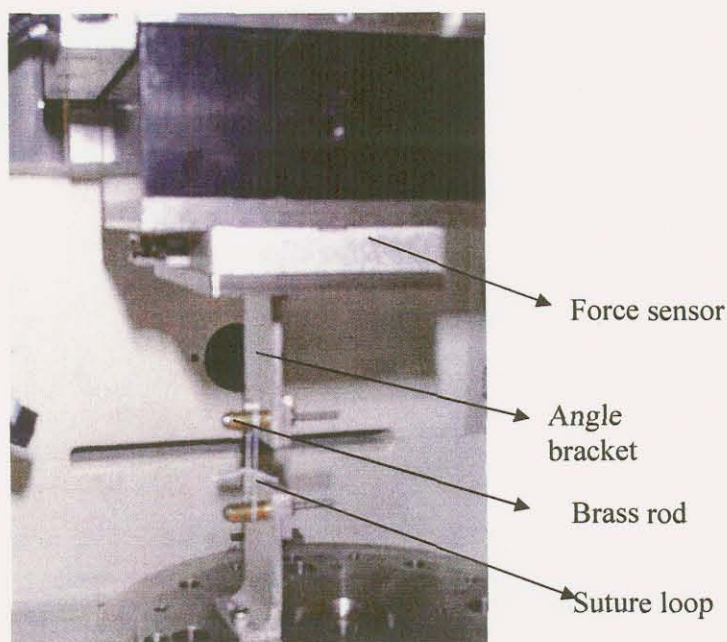


Figure 4. Test set up for knot slippage strength measurement

# **EXHIBIT 3 – Part 2 of 7**



## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

The typical force response curves as recorded during the experiments are presented in the fig. 5 below.

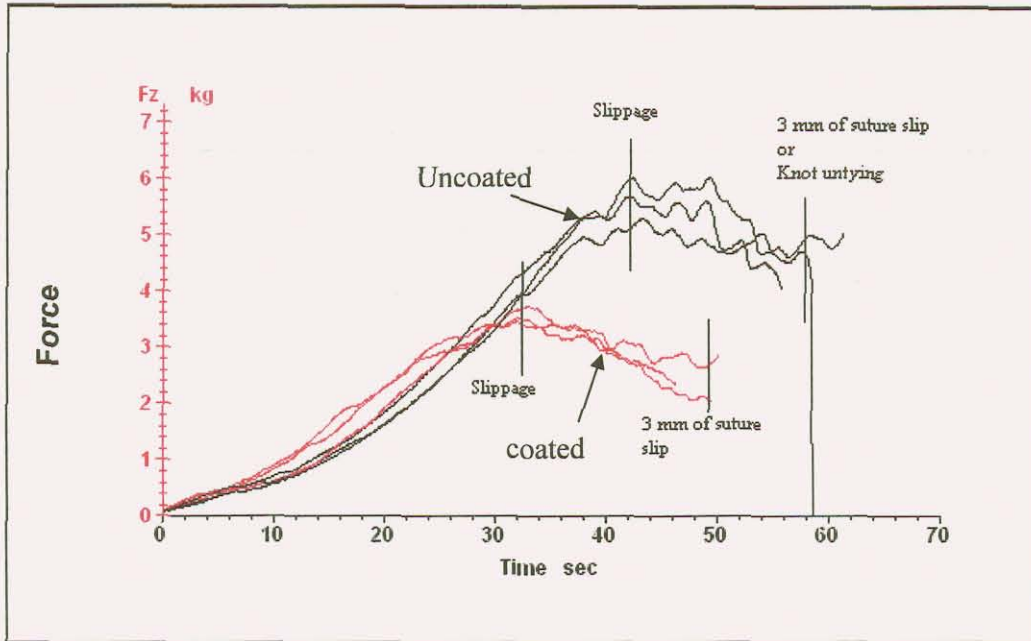


Figure 5. Typical data for force at slippage and knot failure for coated and uncoated sutures

The knot strength values as determined from the curves are summarized in the Table 2 below.

Table 2. Knot strength data for coated and uncoated sutures

Exp #	Knot strength (kg)			
	at slippage		at knot failure	
	Coated	Uncoated	Coated	Uncoated
1	3.52	5.33	3.06	4.09
2	2.36	4.97	2.03	4.09
3	3.46	4.80	3.15	2.42
4	4.25	6.04	2.07	2.98
5	3.74	4.70	2.40	3.53
6	2.43	5.36	2.77	4.79
7	3.47	4.86	2.09	3.45
8	3.27	5.10	2.64	3.90
Average	3.31 ± 0.95	5.14 ± 0.67	2.52 ± 0.56	3.36 ± 1.19





## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

From the above data it can be concluded that the knots tied using the coated sutures slipped and failed at lower forces when compared to the knots tied using uncoated sutures. The experimental data compare well with the data reported in the previous works [2, 3].

### 7. Knot Run-down Tests

The suture was tied with a 'half hitch knot' as shown in fig. 6 [4] around a supplemental cylinder with a 2.5 cm diameter. The loop thus formed was then slipped off the supplemental cylinder and placed on the lower brass rod of the UMT-2 testing machine. The knot was then subjected to running-down by pulling at a constant speed of 1.5 mm/sec on the longer free end in the testing machine as shown in fig. 7. The test procedure was based on the description provided in the literature [5]. The pulling force was continuously recorded as the knot traveled down the suture. Chatter or variation in knot run-down force was also noted.



Half-hitch

Figure 6. Half-hitch tied for the knot run-down tests

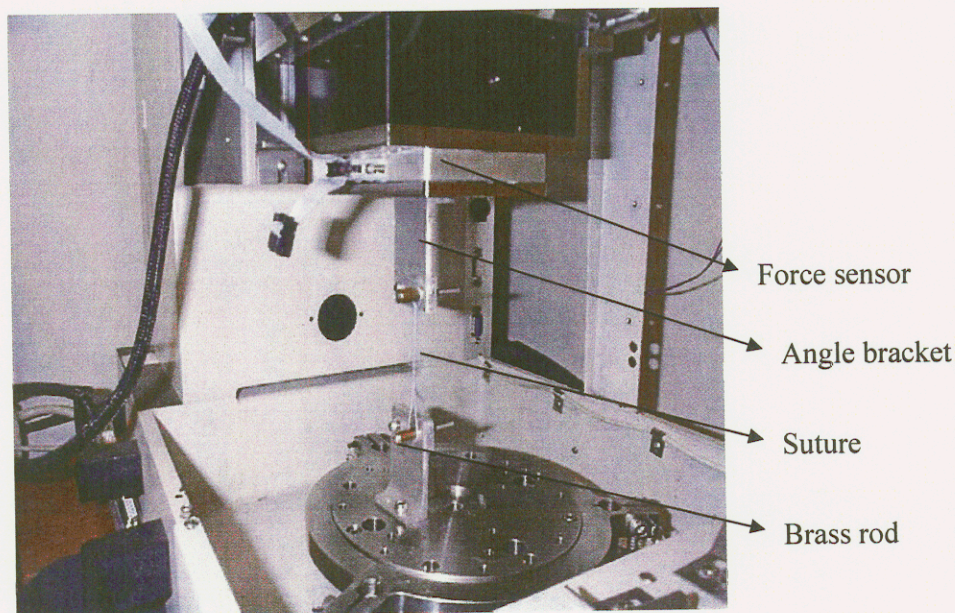


Figure 7. Test set up for the knot run-down test





# CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

The typical pulling force data from the tests performed on coated and uncoated sutures plotted versus time is shown in fig. 8 below:

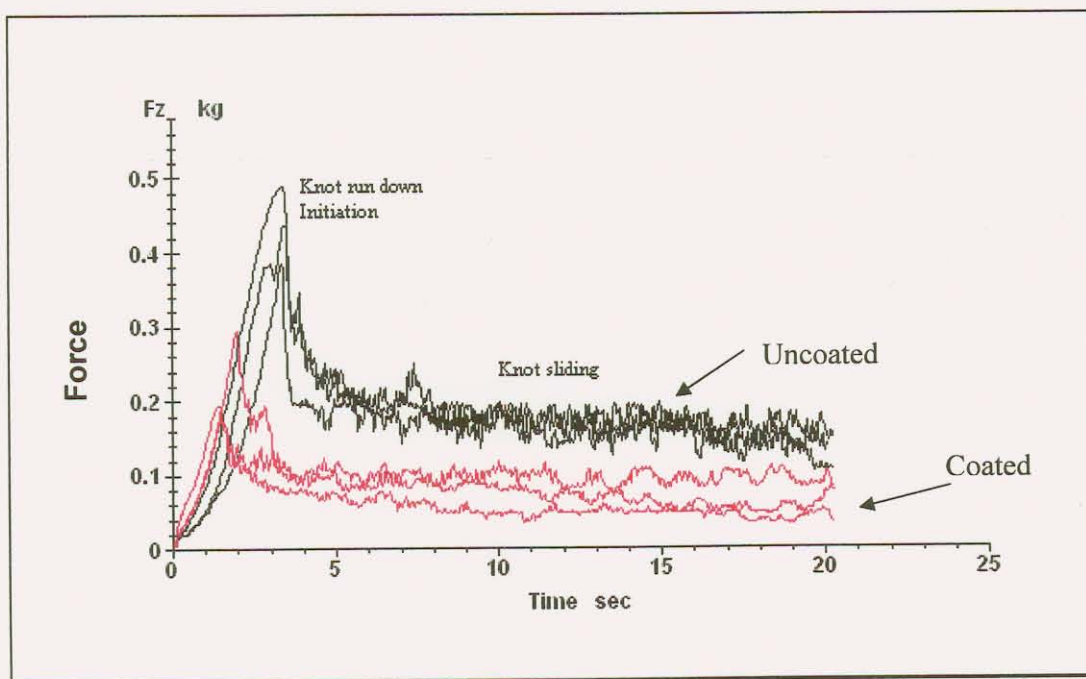


Figure 8. Force versus time for coated and uncoated sutures during knot run-down experiments

The force when the knot begins to slide over the suture was noted from the pulling force data. This gives the run-down force. The run-down force values as measured from the test data are tabulated in the Table. 3 below:

Table 3. Knot run-down test data

Exp #	Run-down force (kg)	
	Coated suture	Uncoated suture
1	0.28	0.39
2	0.20	0.54
3	0.26	0.42
4	0.22	0.49
6	0.18	0.44
7	0.19	0.28
8	0.21	0.26
average	$0.22 \pm 0.05$	$0.40 \pm 0.14$



## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

As can be seen from the above result, the coated sutures had lower run-down force when compared to the uncoated sutures.

### 8. Friction tests

The schematic of suture-on-suture testing set-up is shown in the fig. 9 below.

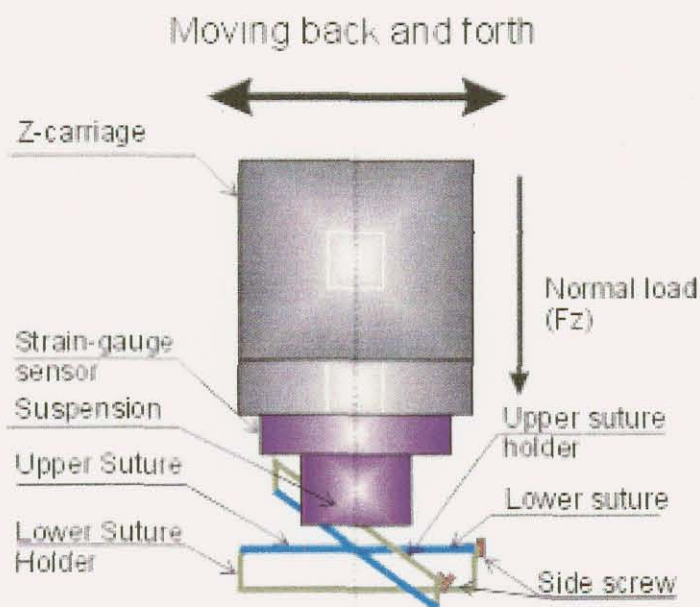


Figure 9. Test schematic for measuring suture-on-suture friction

A sample of suture was mounted and tensioned on the upper sample holder and another sample of the same suture was mounted and tensioned on the lower sample holder. The tension of both the sutures was adjusted using side screws to ensure constant tension for each suture, as shown in fig. 10. The upper suture was moved on the lower one back and forth with a reciprocating length of 3 mm at a frequency of 0.5 Hz under a constant normal load of 2 N (0.2 kg) for 200 seconds. A close-loop feedback loading mechanism ensured a constant normal force.

Both the applied vertical load and friction (shear) response force were continuously monitored and recorded during the tests.



# CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

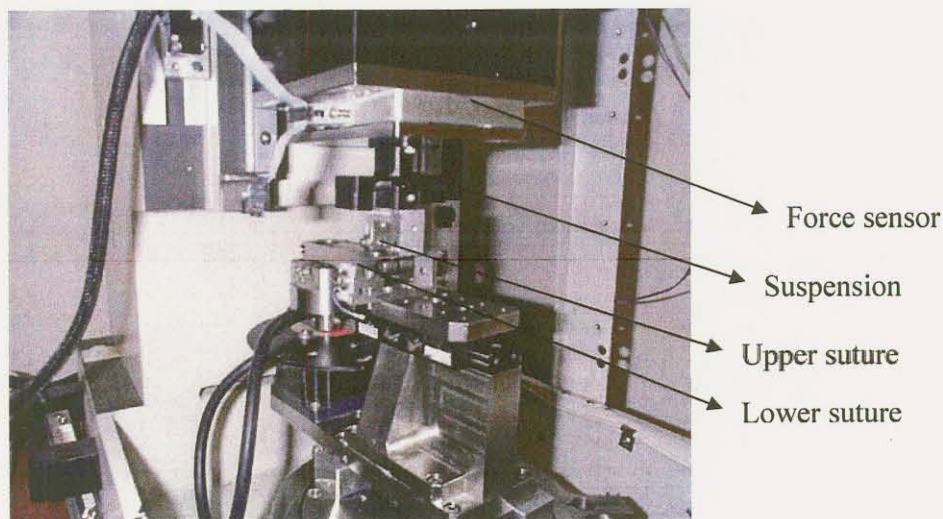


Figure 10. Set up of suture-on-suture friction tests

The coefficient of friction curves as recorded during the reciprocating tests are presented in fig. 11 below. The uncoated sutures had higher average coefficient of friction. The numerical data from the tests are noted and summarized in table. 4

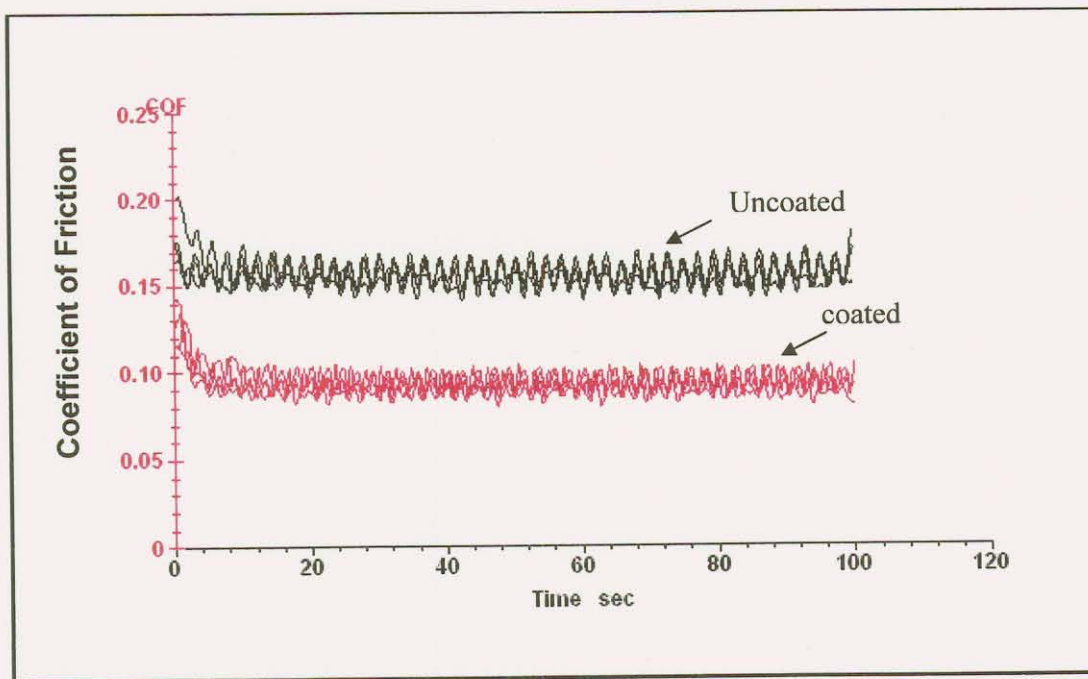


Figure 11. Typical Coefficient of Friction curves for Coated and Uncoated Sutures

# **EXHIBIT 3 – Part 3 of 7**





## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

Table 4: Average coefficient of friction data from suture-on-suture tests

Exp #	Coefficient of Friction	
	Coated suture	Uncoated suture
1	0.09	0.15
2	0.10	0.17
3	0.08	0.16
4	0.10	0.16
5	0.09	0.16
6	0.09	0.16
7	0.09	0.17
8	0.10	0.17
Average	$0.09 \pm 0.01$	$0.16 \pm 0.01$

From the above results, it can be seen that the coated sutures have lower coefficient of friction when compared to the uncoated sutures. This result correlates well with the run-down force data in the previous section. The average coefficient of friction data is similar to the previous data [1, 6].

### 9. Chatter Data

Chatter is termed as the variation in friction during knot run-down and/or reciprocating friction tests. These variations are due to stick-slip process between the interacting suture surfaces when the knot is tied-down [5]. The difference between the maximum and the minimum friction coefficients, or amplitude of frictional auto-oscillations, is the measure of the chatter. Chatter data measured from both the knot run-down and the suture-on-suture friction tests are summarized in the table 5 below.

Table 5: Chatter data from knot run-down and suture-on-suture tests

Test #	Chatter data	
	Coated suture	Uncoated suture
1	0.009	0.013
2	0.009	0.017
3	0.008	0.013
4	0.008	0.013
5	0.010	0.012
6	0.012	0.011
7	0.008	0.014
8	0.010	0.019
average	$0.009 \pm 0.001$	$0.014 \pm 0.003$



## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

The chatter was higher for the uncoated sutures when compared to the coated ones. This result strengthens the conclusion from the previous results that coated sutures provide greater ease of handling during surgical use.

### 10. Tissue Drag Tests

The frictional force encountered during the passage of the suture through a tissue is termed as tissue drag. A 20-mm length of suture was pulled through a piece of leather at a constant rate of 1 mm/sec, while continuously recording the pulling force. The test procedure is based on the description provided in the previous works [7]. The leather piece was held in position using fixtures as shown in fig. 12. Two types of tests were performed: dragging the suture through the hole made with a needle and dragging the suture between two tightly clamped pieces of leather. In both cases, the upper end of the suture was attached to the UMT upper bracket providing the well-controlled motorized dragging action. The average drag force measured in both types of experiments was identical.

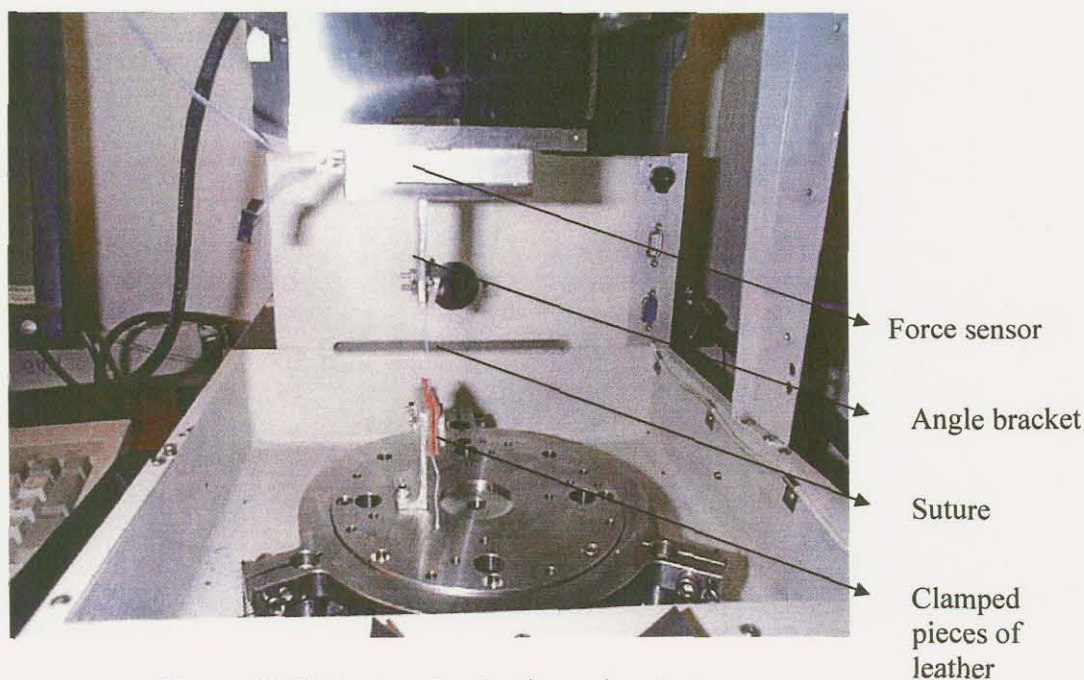


Figure 12. Test set up for the tissue drag test

Fig. 13 presents the force required to pull the coated and uncoated sutures. The highest force recorded gives a measure of the static drag force that was necessary to overcome in order to initiate the suture motion through the leather. The dynamic drag force was measured during the motion of the suture. The average static and dynamic drag forces are summarized in Table 6. The data are comparable to the previously reported results [1].





## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

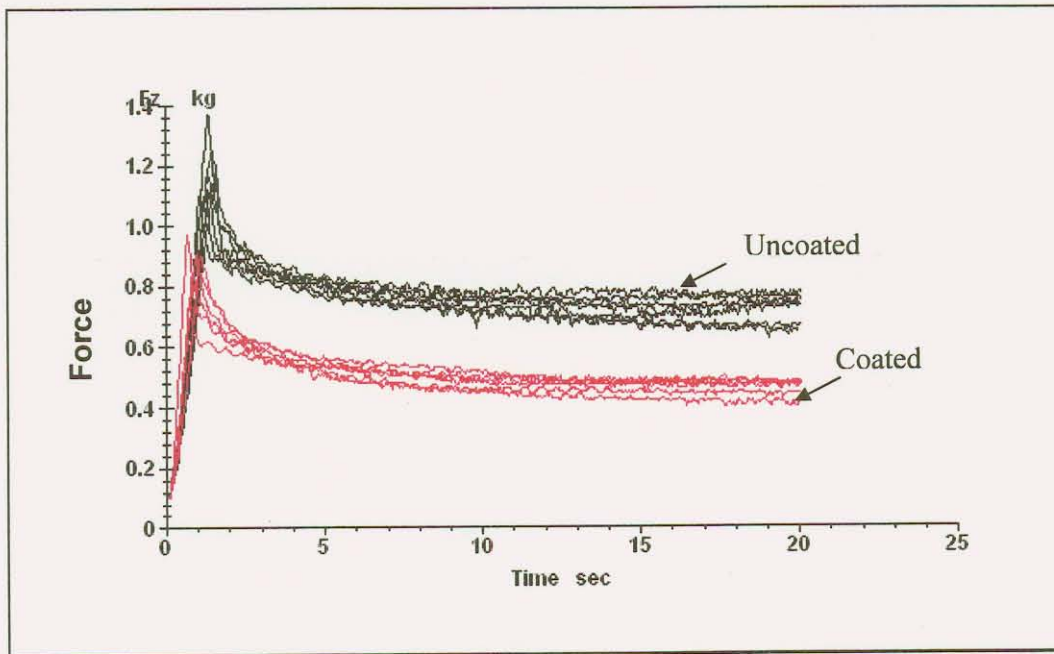


Figure 13. Typical force curves for coated and uncoated sutures.

Table 6. Drag force from the tissue drag tests

Exp #	Drag force (kg)			
	Static		Dynamic	
	Coated suture	Uncoated suture	Coated suture	Uncoated suture
1	1.10	1.15	0.55	0.74
2	0.85	1.20	0.52	0.78
3	0.71	1.19	0.41	0.84
4	0.68	1.39	0.46	0.91
5	0.97	1.10	0.46	0.85
6	1.11	1.19	0.58	0.64
7	0.90	1.13	0.51	0.77
8	0.92	1.13	0.50	0.72
Average	$0.91 \pm 0.20$	$1.18 \pm 0.15$	$0.50 \pm 0.11$	$0.78 \pm 0.14$

### 11. Microscopy Data

We have attempted to study the structure of the sutures with a digital optical microscope, attached to the same UMT tester, but the structure was undistinguishable. So, we utilized

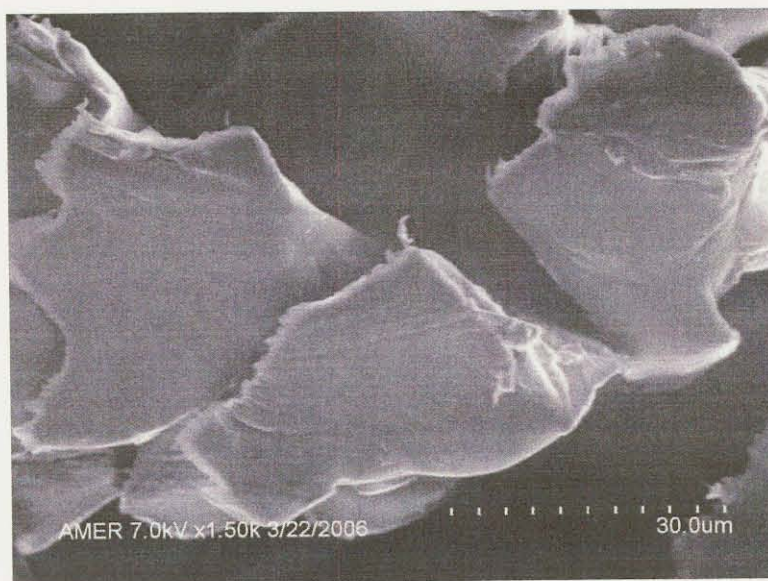
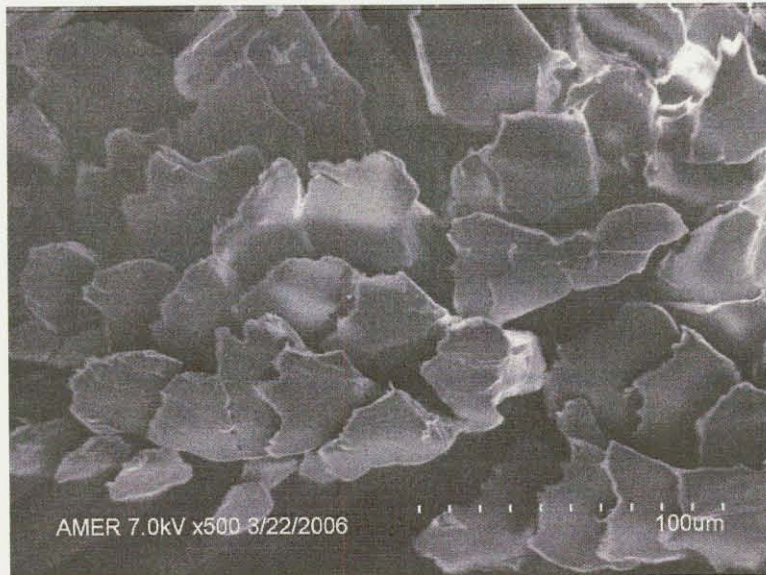


**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

laboratory imaging services of a reputable local analytical lab AMER in Sunnyvale, California. Dr. Gitis brought samples of the uncoated and coated sutures to AMER and was present there all the time while their lab engineer Tony Lin performed SEM (scanning electron microscopy) imaging.

The obtained images are presented below in figures 14 and 15.



**Figure 14. SEM Photos of the Coated Suture**





**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

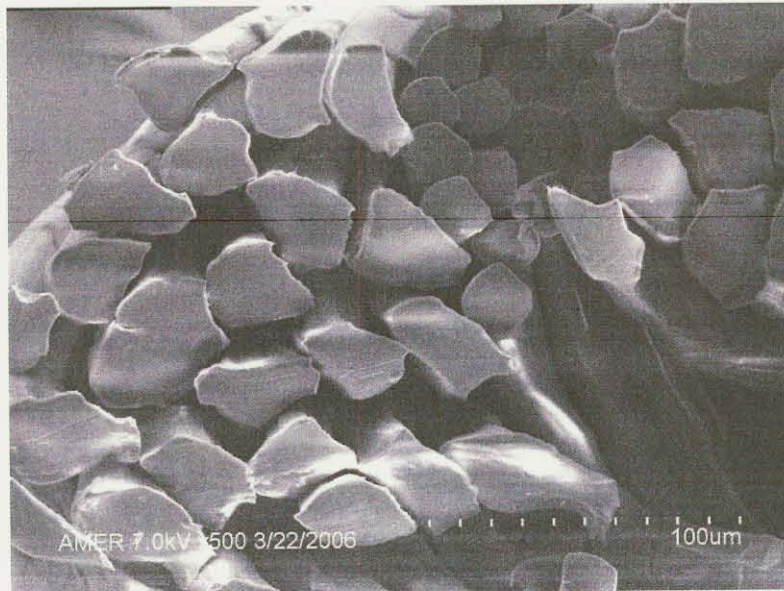


Figure 15. SEM Photos of Uncoated Sutures

## 12. Statistical Significance of Test Data

We used a common t-distribution statistical analysis, assuming the test data to be normally distributed. The t-analysis assesses whether the means of two data groups are statistically

# **EXHIBIT 3 – Part 4 of 7**



## CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

different from each other. Then the test statistic (t-value) is calculated as [8, 9]:

$$t = \frac{X_u - X_c}{\sqrt{\frac{V_c}{N_c} + \frac{V_u}{N_u}}}$$

where  $X_c$  and  $V_c$  - mean and variance, correspondingly, of data for coated suture,  
 $X_u$  and  $V_u$  - mean and variance, correspondingly, of data for uncoated suture,  
 $N_c$  and  $N_u$  - number of tests for coated and uncoated sutures, correspondingly ( $N = 8$ ).

The calculated t-values for all our test data are presented in Table 7 below.

Table 7. Comparison of t-values for data significance

Test	Coated		Uncoated		Experimental "t"-value	"T" threshold
	$X_c$	$V_c$	$X_u$	$V_u$	t	T
Stiffness	6.06 E-6	6.17 E -13	9.93 E-6	1.6 E -12	7.35	1.76
Slippage Strength	3.31	0.41	5.14	0.19	6.72	1.76
Untie Strength	2.52	0.2	3.66	0.54	3.72	1.76
Run-down Force	0.22	0.001	0.4	0.01	4.62	1.76
Friction	0.09	3.58 E -5	0.16	5.66 E -5	20.27	1.76
Chatter	0.009	1.58 E -6	0.014	6.91 E -6	4.63	1.76
Static drag	0.91	0.025	1.18	0.008	4.29	1.76
Dynamic drag	0.5	0.003	0.78	0.007	7.91	1.76

To make a conclusion that the difference between groups of data is statistically significant, the t-value should be larger when compared to a T-threshold calculated based on the degrees of freedom of the distribution and an error level. Degrees of freedom is calculated as [8]: DoF =





CENTER FOR TRIBOLOGY, INC.

1715 Dell Avenue  
Campbell, CA 95008 USA  
(408) 376-4040 Tel • (408) 376-4050 Fax

$N_c + N_u - 2 = 14$ . An error level of 0.05 (5%) is most commonly used. Based on the DoF and error level, the T-threshold is found from a standard t-distribution table [8, 9] to be  $T = 1.76$ .

As seen from the Table 7, the computed t-values of test data are much greater than the threshold T level, which allows us to conclude that the observed differences between coated and uncoated sutures are statistically significant.

*Norm Gitis*

Dr. Norm Gitis  
President, Center for Tribology, Inc.  
Chairman, STLE Technical Committee on Tribotesting

**References:**

1. George Rodeheaver et al, Journal of Surgical Research 35, 525-530 (1983)
2. Arthroscopy: The Journal of Arthroscopic and Related Surgery Vol. 16, No 2, (2000), pp 202-207
3. Schubert et al, American Journal of Obstetrics and Gynecology, Vol.187, ( 6), (2002), 1439
4. [www.ukvet.co.uk/ukvet/articles/surgery\\_suture%20patterns.pdf](http://www.ukvet.co.uk/ukvet/articles/surgery_suture%20patterns.pdf)
5. Perciaccante et al, US patent No: 4,047,533, September 1977
6. [http://www.cetr.com/Brochures/Mechanical\\_Tester\\_for\\_Bio-Medical\\_Materials\\_and\\_Devices.htm](http://www.cetr.com/Brochures/Mechanical_Tester_for_Bio-Medical_Materials_and_Devices.htm)
7. Rao Bezwada et al, Biomaterials 16 (1995) 1141-1148
8. [http://www.socialresearchmethods.net/kb/stat\\_t.htm](http://www.socialresearchmethods.net/kb/stat_t.htm)
9. Douglas Montgomery, Design and Analysis of Experiments, John Wiley & sons, Inc.

**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

**CETR Confidential****Appendix 1. CETR Customers, 1993 – 2006**

No.	Customer	State/Country			
1	3M Corporation	Minnesota, Singapore	68	First Automobile Works	China
2	ABB Flexible Automation	Michigan	69	Flex Foot	California
3	Abrasive Technology	Ohio	70	Ford Visteon	Michigan
4	Advanced Elastomer Systems	Ohio	71	FormFactor	California
5	Advanced Refractory Technologies	New York	72	Fuji Electric	Japan, Malaysia
6	Advanced Surface Microscopy	Indiana	73	Fujitsu	Japan
7	Advanced Urological	California	74	Function Engineering	California
8	Akashic Memories	California	75	General Electric	New York
9	Alcatel	California	76	General Motors	Michigan
10	Alcoa	Pennsylvania	77	Gillette	Massachusetts
11	Alps	Japan	78	GOJO Industries	Ohio
12	Alvyn	California	79	Greene, Tweed & Co	Pennsylvania
13	Ampex	California	80	Guardian Industries	Michigan
14	Apple Computer	California	81	Guidant	Minnesota
15	Applied Magnetics	California	82	H.B. Fuller Co	Minnesota
16	Applied Material Technologies	California	83	Hares Group	Ukraine
17	Applied Materials	California	84	Harris Corporation	Florida
18	Applied MicroStructures	California	85	Headway	California
19	Ararat Industrial	Mexico	86	Henan University	China
20	Asahi-Komag	Japan	87	Henkel Surface Technologies	Michigan
21	ATMI	Texas	88	Hewlett Packard	CA, ID, OR, WA, Singapore
22	Atrua Technologies	California	89	Hitachi	Japan, California
23	Auto Wax	Texas	90	Hitachi Metals	Japan
24	Bausch & Lomb	New York	91	HMT Technology	California
25	Bell Microproducts	California	92	Hoffmann & Co	Austria
26	Borg Warner Automotive	New York	93	Honeywell Aerospace	Arizona
27	Cabot Microelectronics	Illinois	94	Honeywell Automotive	Ohio
28	Carbone of America	Virginia	95	Howmet Casting	Michigan
29	Cargill	Minnesota	96	Hoya	Japan, California
30	Cartesian Data	California	97	Hyper-Therm HTC	California
31	Castlewood Systems	California	98	Hyundai Motor	South Korea
32	Castrol North America	Illinois, New Jersey	99	IBM	California, New York, China
33	Censtar	California	100	ICI Chemicals	United Kingdom
34	Chevron	California	101	Imation	Minnesota
35	China Univ. of Mining Technology	China	102	Imperial Oil	Canada
36	City of San Francisco	California	103	Infineon Technologies	Germany
37	Climax Research	Michigan	104	Infineum	United Kingdom
38	Colorado School of Mines	Colorado	105	Intel	Oregon
39	Conner Peripherals	California	106	Interactive Flight Technology	Arizona
40	Conner Technology	Colorado	107	Intermec	Washington
41	Coming	New York	108	Iomega	Utah, California, Malaysia
42	Creare	New Hampshire	109	JDS Uniphase	California
43	CTC Consultants	California	110	JiLin University	China
44	Dalian University of Technology	China	111	JSR Micro	California, Japan
45	Dana Corporation	Ohio	112	JTS	California
46	DAS Devices	California	113	Juniper Networks, Inc.	California
47	Dell Computer	Texas	114	K2 Optronics	California
48	Delphi Harrison	New York	115	Kaifa	China
49	Denso	Japan	116	Kanagawa Industrial Research Institute	Japan
50	Digital Papyrus	California	117	Katsina Optics	California
51	Dow Chemical	Michigan	118	Kobe Steel	California, Japan
52	Draper Laboratory	Massachusetts	119	Komag	California, Malaysia
53	Dresden Technical University	Germany	120	Konica	Japan
54	DuPont	Delaware, New Jersey	121	Korea Research Institute of Chemical Technology	South Korea
55	Dyneon	Minnesota	122	Korea Testing Laboratory	South Korea
56	Eastman Kodak	New York	123	Korean Institute of Science & Tech.	South Korea
57	Ecolab	Minneapolis	124	Kubota	Japan
58	EKC Technology	California	125	Kuwait University	Kuwait
59	Elpida Memory	Japan	126	Lam Research	California
60	Embraco	Brazil	127	Lanzhou Inst. Chemical Physics	China
61	Essilor	France	128	Louisiana State University	Louisiana
62	Ethicon	New Jersey	129	Loyola Marymount University	California
63	ETH-Zurich	Switzerland	130	Lucent Technologies	New Jersey, New York
64	ExcelStar Technology	Colorado	131	Luleå University of Technology	Sweden
65	Exponent	Florida, Massachusetts			
66	ExxonMobil	New Jersey			
67	Federal-Mogul	Michigan			



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential**

132	Mahle Metal Leve	Brazil	201	Science & Technology Park of Venice VEGA	Italy
133	Mannheim Univ. Applied Sciences	Germany			CA, CO, MN, OK,
134	MarQlin	California			Brittan, Ireland,
135	Marquez Glasseries	Maryland	202	Seagate Technology	Thailand, Singapore
136	MAT	Japan			Texas
137	Matsushita Electronics	Japan	203	Sematech International	Florida
138	Maxtor	California, Colorado	204	Sensomatic Electronics	Oregon
139	Medtronic	California	205	Sequent Computer	China
140	Michelin	Russia	206	Shanghai Inst. Technical Physics	China
141	Micropolis	California, Singapore	207	Shanghai Institute Microsystems	China
142	MicroStor	California	208	Sharp	Japan
143	MIT	Massachusetts	209	Shenyang Inst. Metal Research	China
144	Mitsubishi Chemical	Japan, California	210	Shinhan Diamond	South Korea
145	Mitsumi Electronics	Japan	211	Showa Denko	Japan, Singapore
146	MMC Technology	California	212	Siemens	California
147	MMR Technologies	California	213	Silicon Valley Export Witness Group	California
148	Morganite	North Carolina	214	Singapore Institute Manufacturing Technology (SIMTech)	Singapore
149	Moscow State University	Russia	215	Siros	California
150	MRCC	North Carolina	216	SKW Associates	California
151	MTEC	Thailand	217	Sony	Japan
152	Nalco Chemical	Illinois	218	Southern Illinois University	Illinois
153	Nanjing University of Aeronautics	China	219	Southwest Jia-Tong University	China
154	Nanyang Technological Univ.	Singapore	220	Space Research Institute # 510	China
155	NASA	California, Maryland	221	SpeedFam-IPEC	Arizona
156	National Inst. for Space Research	Brazil	222	St.Jude Medical	Minnesota
157	National Institute of Advanced Industrial Science & Technology	Japan	223	Stanford University	California
158	National University of Singapore	Singapore	224	State University of New York	New York
159	Near Inc.	California	225	StorCard	California
160	NEC	Japan, California	226	StorMedia	California
161	Network Associates	California	227	Sub-One Technology	California
162	New Focus	California	228	Sulzer Metco	New York
163	NHK	Japan	229	SurMet	Massachusetts
164	NICS Electronics	South Korea	230	Swales Aerospace	Maryland
165	Nippon Sheet Glass	Japan	231	Symphonix	California
166	NOK	Japan	232	SyQuest	California
167	North Carolina A&T State Univ.	North Carolina	233	TDK	Japan
168	Northeastern University	Massachusetts	234	Teletronics	Colorado
169	Northwestern University	Illinois	235	TeraStor	California
170	Novellus	Oregon	236	Torlys	Canada
171	Nye Lubricants	Massachusetts	237	Toshiba	Japan, California
172	Optobionics	California	238	Trace Storage	Taiwan, California
173	Owens-Illinois	Ohio	239	Turtle Wax	Illinois
174	Pennzoil-Quaker	Texas	240	Tyco Fire and Security	Florida
175	PerkinElmer Optoelectronics	Canada	241	Ultramet	California
176	PhaseMetric	California	242	Unilever	New Jersey
177	Philips Multimedia	California	243	United States Surgical	Connecticut
178	Piper Plastics	Arizona	244	University of Alabama	Alabama
179	Plasma Technology Inc.	California	245	University of Alaska	Alaska
180	Praxair	Indiana	246	University of Alberta	Canada
181	PRI Automation	California	247	University of Arizona	Arizona
182	Procter & Gamble	Ohio	248	University of California	California
183	Qualcomm	California	249	University of Idaho	Idaho
184	Quantum	California, Massachusetts	250	University of Leoben	Austria
185	Quinta	California	251	University of Modena	Italy
186	RadiSys	Oregon	252	University of Nottingham	England
187	Rain Bird Sprinkler	California	253	University of South Carolina	South Carolina
188	Raychem	California	254	University of South Florida	Florida
189	Read-Rite	California, Japan, Thailand	255	University of Sydney	Australia
190	Reset	California	256	University of Ulster	United Kingdom
191	RioSpring	California	257	Varian	California
192	Ritek	Taiwan	258	Verbatim	California
193	Rohm & Haas	Delaware	259	Veridicom	California
194	Rolex	Switzerland	260	Vichem-GelPak	California
195	Royal Canadian Mint	Canada	261	Victrex	United Kingdom
196	SAE Magnetics	California, China	262	Vigabyte International	California
197	Saesol Diamond	Korea	263	Western Digital	CA, Singapore, Thailand
198	Saint-Gobain Perform. Plastics	California	264	Western Michigan University	Michigan
199	Samsung	California, South Korea	265	Yonsei University	South Korea
200	Schick & Wilkinson Sword	Connecticut			



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

CETR Confidential**Appendix 2a. CV of Dr. Norm V. Gitis**Education

Ph.D., Mechanical Engineering & Tribology	1983	USSR Academy of Sciences
M.S., Mechanical Engineering	1978	USSR Polytechnic University

Doctoral Dissertation

Surface Roughness Optimization for Boundary-Lubricated Friction Joints, Moscow, 1983.

Employment History

Center for Tribology, Inc., Campbell	2000-now	President & CEO
Center for Tribology, Inc., Mountain View	1994-2000	President & Founder
Maxtor, San Jose	1992-1993	Tribology Manager
IBM, San Jose	1989-1992	Advisory Engineer
USSR Center for Machine Tools and Robotics, Moscow	1984-1988	Senior Lead Scientist
Petrochemical University, Moscow	1986-1988	Adjunct Professor
Tribology Center of USSR Academy of Sciences, Moscow	1978-1983	Research Scientist

Professional Society/Committee Membership

Chairman, Technical Committee on Tribotesting, Society of Tribologists and Lubrication Engineers	1998 - 2005
Vice-Chair, G-02.40 Subcommittee on Wear, ASTM	2000 - 2004
Member, Research Committee on Tribology, American Society of Mechanical Engineers	1996 - 1998
Member, Tribology Division, American Society of Mechanical Engineers	1991 - 2000
Member, Society of Tribologists and Lubrication Engineers	1990 - 2005
Member, International Disk Drive Equipment and Materials Association	1993 - 2005

Technical Conferences/Symposia

Chairman and/or organizer of 23 international tribology and tribo-metrology meetings and symposia (see table attached) in the United States (Detroit, Hawaii, Houston, Las Vegas, Los Angeles, Nashville, New York, Orlando, Pittsburgh, San Jose), Austria (Vienna), Canada (Calgary, Toronto), Japan (Morioka, Yokohama, Kobe), Uzbekistan (Tashkent). Organizer of 28 technical sessions at 11 STLE annual meetings (1993-1994, 1998-2006).

Technical Presentations

Invited speaker at over 70 international conferences and symposia, 55 seminars at major universities and academic research centers, 170 major industrial research engineering centers of corporations in the USA, as well as Austria, China, Germany, Ireland, Japan, Korea, Netherlands, Russia, Singapore, Taiwan, Thailand (see table attached).

CEO of #1 Fastest Growing Private Company in Silicon Valley, 1997.

Guest Professor at JiLin University, China, 2002.

Honorary Member of Japanese Society of Tribologists, 1992.

Summa Cum Laude Graduation, Russia, 1978.

# **EXHIBIT 3 – Part 5 of 7**



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential****Patents****USA Patents (Related to Tribotesting)**

1. *Patent No 6,502,455* of Jan 7, 2003. Microscratch Test Method and Indenter, (with M. Vinogradov), filed Sept 25, 2000.
2. *Patent No 6,418,776* of Jul 16, 2002. Method and Apparatus for Measuring Friction and Wear, (with M. Vinogradov, et al), filed July 24, 2000.
3. *Patent No 6,363,798* of Apr 2, 2002. Method and Device for Measuring Forces, (with M. Vinogradov, et al), filed July 24, 2000.
4. *Patent No 6,324,918* of Dec 4, 2001. Bi-directional Force Sensor, (with M. Vinogradov, et al.), filed June 5, 2000.
5. *Patent No 5,795,990* of Aug 18, 1998. Method and Apparatus for Measuring Friction and Wear Characteristics of Materials, (with L. Levinson, et al.), filed July 30, 1997.

**USA Patents (Related to Precision Polishing)**

1. *Patent No 6,702,646* of March 9, 2004. Method and Apparatus for Monitoring Polishing Plate Condition, (with M. Vinogradov), filed July 1, 2002.
2. *Patent No 6,585,562* of July 1, 2003. Method and Apparatus for Polishing Control With Signal Peak Analysis, (with M. Vinogradov), filed Sept 17, 2001.
3. *Patent No 6,494,765* of Dec 17, 2002. Method and Apparatus for Polishing Control, (with M. Vinogradov), filed May 17, 2001.
4. *Patent No 6,257,953* of July 10, 2001. Method and Apparatus for Controlled Polishing, (with M. Vinogradov), filed Sept 25, 2000.

**USA Patents (Related to Magnetic Disk Drives)**

1. *Patent No 6,559,108* of May 6, 2003. Perfluoropolyether Compounds as Magnetic Media Lubricants, (with J. Howell, et al.), filed Nov 15, 2000.
2. *Patent No 5,455,727* of Oct.3, 1995. Transducer-Suspension Assembly, (with D. Baral, et al.), filed Aug.9, 1994.

**USA Patents (Related to Particle Detection)**

1. *Patent No 6,573,836* of June 3, 2003. Method and Apparatus for Detecting The Presence of Powdered Material, (with R. Mavliev, et al.), filed Jan 4, 2002.

**USA Patents (Related to Surgical Instruments)**

1. Patent Pending. Multi-portal Device and Method for Percutaneous Surgery, (with T. Alamin, et al), filed May 10, 2002.
2. Patent Pending. Multi-portal Device with Linked Cannulae and Method for Percutaneous Surgery, (with T. Alamin, et al), filed May 21, 2002.

**USSR Patents (Related to Antifriction Coatings and Designs)**

1. *Patent No 1,545,576*. Composition for an Antifrictional Composite Material, (with A. Lapidus, et al.). Priority 3/14/88, registered 10/22/89, unpublished as state secret.
2. *Patent No 1,490,924*. Epoxy Compound for Antifrictional Wear-Resistant Coatings, (with A. Lapidus, et al.). Priority 9/7/87, registered 3/1/89, unpublished as state secret.
3. *Patent No 1,436,654*. Magnetic Device for Unloading of Frictional Joints, (with A. Lapidus, et al.). Priority 6/7/87, registered 8/4/88, unpublished as state secret.
4. *Patent No 1,413,830*. Method of Mechanical Treatment of Machine Tool Slideways, (with D. Levit and B. Fragin). Published Bull. 28, 1988.
5. *Patent No 1,368,519*. Sliding Bearing, (with A.Lapidus). Published Bull. 3, 1988.

**USSR Patents (Related to Tribotesting)**

1. *Patent No 1,448,887*. Method for Testing Antifrictional Properties of Lubricants. Priority 12/2/86, registered 9/1/88, unpublished as state secret.



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential**

2. *Patent No 1,377,668*. Test Method for Friction-Induced Vibrations, (with A. Lapidus). Published Bull. 8, 1988.
3. *Patent No 1,352,317*. Method for Monitoring Friction Process, (with G. Saruchev, et al.). Published Bull. 42, 1987.
4. *Patent No 1,307,310*. Method for Monitoring Degree of Seizure, (with B. Chizhov and A. Lapidus). Published Bull. 16, 1987.
5. *Patent No 1,043,566*. Method of Lubricant Testing, (with I. Kragelskii). Published Bull. 35, 1983.
6. *Patent No 1,029,043*. Method and Device for Lubricant Testing, (with N. Alekseev, et al.). Published Bull. 26, 1983.

**List of Publications****Friction Fundamentals and Stick-Slip**

1. Nature of Friction Coefficient: Panel Discussion. *Lubrication Engineering*, 4, 1995, (with C.DellaCorte)
2. Mechanism of Frictional Auto-Oscillations. *Proceed. 6th Internat. Congress on Tribology Eurotrib'93*, Budapest, Vol. 3, 1993, 428 - 433.
3. Nature of Stick-Slip Effect. *Tribology and Mechanics of Magnetic Storage Systems*, Vol. 7, STLE SP-29, 1990, pp. 107 - 113.
4. Discussion on Stick-Slip and Velocity Dependence of Friction at Low Speeds. *Transact. ASME: Journ. of Tribology*, Vol. 113, 1991.
5. Effect of Slideway Materials on Positioning Accuracy of Moving Units in Machine Tools. *Soviet Engineer. Research*, Vol. 9, No 4, 1989, (with B.Chizhov).
6. Self-Induced Vibrations in the Transversing Units on Machine Tool Slideways. *Soviet Engineer. Research*, Vol. 8, No 4, 1988, (with B.Chizhov and A.Lapidus).
7. Study of Characteristics of Mixed Friction in Sliding Guideways. *Soviet Journ. of Friction and Wear*, Vol. 9, No 4, 1988, (with A.Lapidus and B.Chizhov)
8. *FRictionAL AUTO-OSCILLATIONS*, (in Russian), Moscow, Science Press, 1987, (with I.Kragelskii).
9. Investigation into the Characteristics of Mixed Friction in Slideways. *Soviet Engineer. Research*, Vol. 7, No 11, 1987, (with B.Chizhov and A.Lapidus)
10. Effect of Contact Pressure on the Stick-Slip Properties of Sliding Guideways. *Soviet Engineer. Research*, Vol. 7, No 1, 1987, (with B. Chizhov).
11. *METHODS OF FRICTION AND STICK-SLIP REDUCTION IN MACHINE TOOLS*, (in Russian), Moscow, Engineering Press, 1986.
12. Study of Anti-Stick-Slip Properties of Machine Tool Guideway Materials. *Soviet Journ. of Friction and Wear*, Vol. 7, No 5, 1986.

**Metrology of Thin Films and Coatings**

1. In-Situ Quantitative Integrated Nano+Micro Metrology. *Proceed. Intern. Tribology Conf., Kobe, Japan, June 2005*, (with A. Daugela and J. Xiao), p. D13.
2. Integrated Nano-SPM for Nano-Tribology. *Proceed. Intern. Conf. on Micro and Nano-Technology, Vienna, Austria, March 2005*, (with A. Daugela and J. Xiao), p. 385 - 389.
3. Quantitative Nano & Micro Metrology of Thin Films and Coatings. *Proceed. Intern. Conf. on Industrial Tribology, Mumbai, India, December 2004*, (with A. Daugela, A. Sikder and J. Xiao), p. D5.
4. In-Situ Quantitative Integrated Tribo-SPM Nano-Micro Metrology. *Proceed. ASME/STLE Intern. Tribology Conf., Long Beach, October 2004*, (with A. Daugela, A. Sikder and M. Vinogradov).



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential**

5. Tribometry of Thin Films and Coatings. *Proceed. 1<sup>st</sup> Intern. Conf. on Advanced Tribology*,
6. Singapore, December 2004 (with J. Xiao and M. Vinogradov), p. B59.
7. Multi-Sensor Durability Characterization of Thin Diamond-Like Films. *Proceed. ADC/FCI Conf.*, Tsukuba, Japan, August 2003 (with J. Xiao and M. Vinogradov).
8. Multi-Sensor Testing of Thin and Thick Coatings for Adhesion and Delamination. *Proceed. 26<sup>th</sup> Annual Meeting of Adhesion Society*, Myrtle Beach, February 2003 (with J. Xiao and M. Vinogradov).
9. Tribotesting – Latest Advancements and State of the Art. *Proceed. 3<sup>rd</sup> Intern. Conf. on Surface Engineering*, Southwest Jiatong Univ., Chengdu, China, October 2002, (with J. Xiao).

**Surface Roughness and Waviness**

1. Roughness Optimization of Slideways. *Soviet Engineer. Research*, Vol. 5, No 11, 1985, (with A. Lapidus).
2. Influence of the Machining Marks Direction on Friction in Boundary Lubrication. *Soviet Engineer. Research*, Vol. 5, No 3, 1985, (with I. Kragelskii).
3. Use of Acoustic Emission Method to Optimize Friction Surface Microrelief. *Soviet Journ. of Friction and Wear*, Vol. 5, No 5, 1984, (with I. Kragelskii, et al.).
4. *Optimization of Surface Micro-geometry at Boundary Friction*. (In Russian), Ph.D. Thesis. Moscow, Institute of Machine Sciences of the USSR Academy of Sciences, 1983.
5. Investigation and Optimization of Surface Microgeometry. *Quality Control and Properties of Machine Parts*, (in Russian), Kiev, Vol. 3, 1980.
6. Determination of Curvature Radii on the Actual Surfaces of Spur Gears. *Russian Engineer. Journ.*, Vol. 60, No 7, 1980, (with L. Shemper).
7. Changes in Microgeometry of Gear Teeth During Running-in. *Machine Parts*, (in Russian), Vol. 21, 1978, (with J. Kotov and S. Filipovich).

**Lubrication and Lubricants**

1. Investigation of Processes in Thin Lubricant Films and Their Effects on Friction. *Proceed. 8th Confer. on Colloidal Chemistry and Physico-Chemical Mechanics*, (in Russian), Tashkent, 1983, (with I. Kragelskii).
2. Calculations of the Activation Energy for a Film Starvation Effect. *Tribotechnics for Engineering*, (in Russian), Moscow, 1983, (with I. Bujanovskii and A. Ginzburg).
3. Investigation of the Film Starvation and its Prevention. *Tribotechnics for Engineering*, (in Russian), Moscow, 1983.
4. Evaluation of Film Starvation Tendency of Greases. *Soviet Journ. of Friction and Wear*, Vol. 4, No 1, 1983, (with I. Kragelskii).
5. Evaluation of Anti-Frictional Properties of Lubricants, (in Russian). *Theoretical and Applied Problems of Wear-Resistance in Engineering*, Leningrad, 1982.
6. Evaluation of Antifrictional Properties of Thin Lubricant Films. *Soviet Physics Articles / USSR Academy of Sciences*, Vol. 27, No 8, 1982, (with I. Kragelskii).
7. An Experimental Study of the Film Starvation Effect. *Soviet Journ. of Friction and Wear*, Vol. 3, No 3, 1982, (with I. Kragelskii, et al.).
8. Analytical Model of Film Starvation Conditions for Adsorptive and Chemisorptive Mechanisms of Film Recovery. *Problems of Friction and Wear*, (in Russian), Vol. 21, 1982, (with V. Kelle and I. Kragelskii).

**Antifrictional Materials and Design of Sliding Bearings**

1. Evaluation of Tribological Properties of Bimetals. *Proceed. Intern. Tribology Conf.*, Kobe, Japan, June 2005, (with M. Vinogradov), p. G15.



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

**CETR Confidential**

2. Precision Experimental Measurements of Viscoelastic Properties of Industrial Polymers. *Proceed. 4<sup>th</sup> Intern Conf. Mechanics of Time-Dependent Materials*, Lake Placid, New York, October 2003.
3. Magnetic Unloading of Sliding Bearings and Guideways. *News of Machinebuilding*, (in Russian), No 2, 1991, (with A.Lapidus, et al.).
4. Advances in Tribology: Slideway Design and Unloading Systems. *Emerging Technology in the Soviet Union*, Delphic Ass., Washington, 1990.
5. How Epilamine Coating Affects the Stick-Slip Properties of Slideways. *Soviet Engineer. Research*, Vol. 8, No 9, 1988, (with A.Lapidus and B.Chizhov).
6. *PLASTIC AND COMPOSITE MATERIALS FOR SLIDING GUIDEWAYS*, (in Russian), Moscow, Engineering Press, 1987.
7. Comprehensive Tribological Tests for Slideway Materials. *Tribotechnics for Engineering*, (in Russian), Moscow, 1987.
8. Assessing the Anti-Stick-Slip Properties of Slideway Materials. *Soviet Engineering Research*, Vol. 6, No 3, 1986.
9. Antifrictional Polymers and Composites for Machine Tool Slideways. *Wear in Machines and Methods of Its Reduction*, (in Russian), Brjansk, 1985, (with A.Lapidus, et al.).
10. Increasing the Wear-Resistance of Slideways. *Soviet Engineer. Research*, Vol. 4, No 10, 1984, (with I.Kragelskii).

**Seizure and Scuffing**

1. Investigation of Non-Thermal Seizure in Machines. *Metalcutting Machine Tools*, (in Russian), Vol. 11, Kiev, 1983.
2. Effect of Mechanical Characteristics of Metals on the External Friction Threshold. *Problems of Friction and Wear*, (in Russian), Vol. 22, 1982.
3. Role of Microgeometry in Non-Thermal Seizure Development at Boundary Friction. *Mechanical Sciences - Machinovedeniye*, No 1, 1982.
4. Reliability of Machine Assemblies and External Friction Threshold. *Reliability in Machines*, (in Russian), Kuibyshev, 1981.
5. Evaluation of Non-Thermal Seizure in Spur Gears. *Proceed. Internat. Confer. JUGOMA-80*, (in Serbo-Croatian), Split, 1980, (with I.Kragelskii).
6. Study of Geometric Conditions of the External Friction Threshold for Cylindrical Gearing. *Soviet Journ. of Friction and Wear*, Vol. 1, No 6, 1980, (with I.Kragelskii).

**Wafer Polishing and Planarization**

1. Effects of Slurry Flow Rate and Pad Conditioning Temperature on Dishing, Erosion and Metal Loss During Copper CMP. *Proceed. AVS CMP User Group Symposium, San Jose, October 2005*, (with S. Kuiry, R. Mudhivarthi, M. Vinogradov and A. Kumar).
2. Effect if Slurry Flow Rate on Dishing, Erosion and Metal Loss During Copper CMP Process. *Proceed. VMIC Conference, Fremont, October 2005*, (with R. Mudhivarthi, S. Kuiry, M. Vinogradov and A. Kumar), pp. 367-372.
3. CMP Process and Consumables Evaluation with PadProbe. *Proceed. CMP-MIC Conference, Fremont, February 2005*, (with S. Hosali, E. Busch, M. Vinogradov).
4. CMP Consumables Characterization. *Proceed. CMP-MIC Conference, Fremont, February 2005*, (with S. Kuiry and M. Vinogradov).
5. In-situ Tribological Properties Monitoring and Chemical-Mechanical Characterization of Planarization Process. *Proceed. ASME/STLE Intern. Tribology Conf., Long Beach, October 2004*, (with A. Sikder, A. Daugela and M. Vinogradov).
6. CMP Process and Consumables Evaluation with PadProbe. *Proceed. AVS Intern. Conf. on Microelectronics and Interfaces, Santa Clara, March 2004*, (with J. Fang, K. Davis, etc.).



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential**

7. Advanced Specification and Tests of CMP Retaining Rings. *Proceed. CMP-MIC Conference*, Los Angeles, February 2004, (with J. Xiao, A. Kumar and A. Sikder).
8. CMP Process and Consumables Evaluation with PadProbe. *Proceed. VLSI Multilevel Interconnection 20<sup>th</sup> Annual Conference*, Los Angeles, September 2003, (with J. Fang, K. Davis, etc.)
9. Incoming Inspection of CMP Consumables at the Semiconductor Fab. *Proceed. VLSI Multilevel Interconnection 20<sup>th</sup> Annual Conference*, Los Angeles, September 2003, (with M. Vinogradov).
10. Tribology Issues in CMP. *Semiconductor Fabtech*, Vol. 18, April 2003.
11. Delamination Studies in Cu/Ultra-Low-K Stack. *Proceed. CMP-MIC Conference*, Marina Del Rey, February 2003, (with A. Sikder, P. Zantye, etc.).
12. CMP In-Situ Pad Condition Monitoring with PadProbe. *Proceed. CMP-MIC Conference*, Marina Del Rey, February 2003, (with B. Kalenian, B. Pautsch, etc.).
13. PadProbe for Quantitative Control of Pad Condition and Wear. *Proceed. VLSI Multilevel Interconnection 19<sup>th</sup> Annual Conference*, Singapore, November 2002 (with M. Vinogradov, J. Xiao, A. Meyman).
14. Tribology Case Studies for Copper Removal Optimization. *Proceed. CMP Annual Symposium*, San Jose, October 2002 (with D. Craven, J. Jin).
15. PadProbe for Monitoring and Control of Pad Surfaces. *Proceed. CMP Annual Symposium*, San Jose, October 2002.
16. Quantitative Evaluation of CMP Process and Materials Using a CMP Tester. *Proceed. 2<sup>nd</sup> Intern. Conf. on Microelectronics and Interfaces*, Santa Clara, February 2001 (with M. Vinogradov).
17. Quantitative Evaluation of a CMP Process Using a Bench-top CMP Tester. *Proceed. 6<sup>th</sup> Intern. CMP-MIC Conf. on Chemical-Mechanical Planarization*, March 2001, (with M. Vinogradov).
18. Quantitative Functional Testing of CMP Materials Using a Bench-top CMP Tester. *Proceed. 18<sup>th</sup> Intern. VMIC Conf. on Multilevel Interconnection*, Santa Clara, September 2001 (with M. Vinogradov).

**Tribology of Magnetic Disk Drives**

1. Metrology for Micro-Tribology. *Proceed. MIPE'97*, Tokyo, July 1997, pp. 431-434.
2. Tribology of Near-contact Magnetic Recording. *Proceed. IDEMA Tribology Symposium*, Santa Clara, May 1996, pp. 117 - 130.
3. Challenges of and Ways to Achieve In-contact and Near-contact Recording. *Proceed. IDEMA Head/Media Interface Symposium*, San Jose, September 1994, pp. 47 - 58.
4. Phenomenon of Stiction in a Magnetic Head-Disk Interface. *Proceed. ASME Energy-Sources Conf.*, PD-Vol.61, New Orleans, January 1994, pp. 11- 15.
5. Tribology of a Magnetic Head-Disk Interface with a Smooth Disk. *Proceed. MIT Tribology Symposium*, Cambridge, July 1993.
6. Study of Low Flying Height Using Acoustic Emission and Friction Techniques. *Advances in Information Storage Systems*, Vol. 6, 1995, pp. 107 - 120, (with C. Gerber).
7. Stiction Phenomenon in the Magnetic Disk-Slider Interface. *Proceed. 6th Intern. Congress on Tribology Eurotrib'93*, Budapest, Vol. 3, 1993, pp. 417 - 422.
8. Experimental Study of Stationary Head-Disk Contact in Magnetic Disk Drives. *Transact. ASME: Journ. of Tribology*, Vol. 115, 1993, pp. 214 - 218 (with R. Sonnenfeld).
9. Nature of Static Friction Time-Dependence. *Journ. Physics D: Applied Physics*, Vol. 25, 1992, pp. 605 - 612, (with L. Volpe).

# **EXHIBIT 3 – Part 6 of 7**



**CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**CETR Confidential**

10. A Technique to Study Effects of Volatile Pollutants on Stiction in Magnetic Disk Drives. *Advances in Information Storage Systems*, Vol. 4, 1992, pp. 277 - 289, (with L.Volpe and C.Brown)
11. Long-Term Stiction at the Magnetic Thin-Film Disk-Slider Interface. *Advances in Information Storage Systems*, Vol. 3, 1991, pp. 91 - 106, (with L.Volpe and R.Sonnenfeld).

**Tribology of Biological Materials and Structures**

1. Tribological Studies on Skin: Measurement of the Coefficient of Friction. *Handbook of Non-Invasive Methods and the Skin*, edited by J. Serup, etc., 2<sup>nd</sup> ed., Taylor & Francis, 2006, pp. 215-224.
2. Tribological Studies on Skin: Measurement of the Coefficient of Friction. *Dry Skin and Moisturizers: Chemistry and Function*, edited by M. Loden and H. Maibach, 2<sup>nd</sup> ed., Taylor & Francis, 2005, pp. 431-441.
3. Metrological Studies for Biotribology. *Proceed. Intern. Tribology Conf., Kobe, Japan, June 2005*, p. C14.
4. Tribometrology of Skin. *Tribology & Lubrication Tech*, #2, 2005, pp. 34 - 42 (with R. Sivamani).
5. Tribometrological Studies for Bioengineering. *Proceed. 1<sup>st</sup> Intern. Conf. on Advanced Tribology*, Singapore, December 2004, p.B60.
6. Tribometrology of Skin. *Tribology Transactions*, Vol. 47, #4, 2004, pp. 461 - 469 (with R. Sivamani).
7. Tribometrology of Skin. *Proceed. 4<sup>th</sup> China Intern. Symposium on Tribology*, Nov 2004, pp. 85-97 (with R. Sivamani).
8. Tribometrological Studies in Bioengineering. *Proceed. 10<sup>th</sup> Intern. Congress on Experimental and Applied Mechanics SEM-2004*, June 2004, pp. 1 - 11.
9. Coefficient of Friction: Tribological Studies in Man. *Skin Research and Technology*, Vol. 9, #3, 2003, pp. 227 - 234 (with R. Sivamani, etc.).
10. Friction Coefficient of Skin in Real-Time. *Skin Research and Technology*, Vol. 9, #3, 2003, pp. 235 - 239 (with R. Sivamani, etc.).

**Machine Reliability**

1. Robotized Machine Tools: Nomenclature of Reliability Indices. *Standard of Soviet Engineering Industry RM 2N00-83*, (in Russian), Moscow, 1983, (with V. Tauzhnanskii, et al.)
2. Analytical Selection of Methods to Increase the Machine Tool Reliability. *Metalcutting Machine Tools*, (in Russian), Vol. 10, Kiev, 1982.
3. Machine Tools: Meantime till Repairs. *Standard of Soviet Machinebuilding Industry OST 2N00-13-80*, (in Russian), Moscow, 1980, (with V. Tauzhnanskii, et al.).



**CENTER FOR TRIBOLOGY, INC.**  
 1715 Dell Avenue  
 Campbell, CA 95008, USA  
 Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

### Appendix 2b. Technical Meetings Organized by Dr. Norm Gitis

<b>Dr. Norm V. Gitis Chaired and/or Organized Technical Meetings</b>						
<b>No</b>	<b>Topic of Meeting</b>	<b>Chaired / Organized</b>	<b>Conference/Symposium</b>	<b>Location</b>	<b>Month</b>	<b>Year</b>
1	Bio-Tribology	Chaired 1 session	Internl. Tribology Conference	Kobe, Japan	June	2005
2	Tribotesting	Organized 3 sessions, chaired 1 session	STLE Annual Meeting	Las Vegas, NV, USA	May	2005
3	Polishing Tribo-Metrology	Organized and chaired meeting	ASTM Working Group Meeting on CMP	Fremont, CA, USA	February	2005
4	Polishing Tribo-Metrology	Organized and chaired 1 session	CMP-MIC Conference	Fremont, CA, USA	February	2005
5	Tribotesting	Chaired 1 session	Internl Conf. on Surface Engineering	Shenzhen, China	October	2004
6	Tribotesting	Organized 4 sessions, chaired 2 sessions	STLE Annual Meeting	Toronto, Canada	May	2004
7	Polishing Tribo-Metrology	Organized and chaired 1 session	CMP-MIC Conference	Los Angeles, CA, USA	February	2004
8	Polishing Tribo-Metrology	Organized and chaired 1 session	VMIC Conference	Los Angeles, CA, USA	September	2003
9	Tribotesting	Organized 3 sessions and chaired 2 sessions	STLE Annual Meeting	New York, NY, USA	May	2003
10	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Houston, TX, USA	May	2002
11	Tribotesting	Chaired 1 session	World Tribology Congress	Vienna, Austria	September	2001
12	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Orlando, FL, USA	May	2001
13	Tribotesting	Organized 3 sessions and chaired 1 session	STLE Annual Meeting	Nashville, TN, USA	May	2000
14	Tribotesting	Organized 2 sessions and chaired 1 session	STLE Annual Meeting	Las Vegas, NV, USA	May	1999
15	Tribotesting	Organized 2 sessions and chaired 1 session	STLE Annual Meeting	Detroit, MI, USA	May	1998
16	Tribology of Head-Disk Interface	Organized symposium	IDEMA Tribology Symposium	San Jose, CA, USA	May	1996
17	Tribotesting and Micro-Tribology	Chaired 2 sessions	International Tribology Conference	Yokohama, Japan	October	1995
18	Tribology of Head-Disk Interface	Organized and chaired Plenar Discussion	ASME/STLE Tribology Conference	Hawaii, USA	October	1994
19	Tribology of Head-Disk Interface	Organized and chaired 1 session	Diskcon	San Jose, CA, USA	September	1994
20	Nature of Friction	Organized and chaired Plenar Discussion	STLE Annual Meeting	Pittsburgh, PA, USA	May	1994
21	Nature of Friction	Organized and chaired Plenar Discussion	STLE Annual Meeting	Calgary, Canada	May	1993
22	Micro-Tribology	Chaired 2 sessions	1st International Conf. On Micro-Tribology	Morioka, Japan	October	1992
23	Frictional Oscillations	Organized and chaired 1 session	International Tribology Conference	Tashkent, Uzbekistan	June	1985



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)**Appendix 2c. Dr. Norm Gitis' Presentations**

No	Topic of Presentation	Conference/Company	Location	Month	Year
<b>Conferences and Symposia</b>					
1	Multi-Sensing Micro/Nano-Metrology	Taiwan Conference on Tribology & Materials Technology	Tainan, Taiwan	September	2005
2	Multi-Sensing Micro/Nano-Metrology	International Surface Engineering Congress	St. Paul, MN	August	2005
3	Tribo-Metrology for Bioengineering	International Tribology Conference	Kobe, Japan	June	2005
4	Tribo-Metrology of Lubricants	STLE Annual Meeting	Las Vegas, NV	May	2005
5	Multi-Sensing Micro/Nano-Metrology	STLE Annual Meeting	Las Vegas, NV	May	2005
6	Multi-Sensing Micro/Nano-Metrology	ICMCTF	San Diego, CA	May	2005
7	Tribo-Metrology for CMP Materials Control	MRS Spring Meeting	San Francisco, CA	April	2005
8	Multi-Sensing Micro/Nano-Metrology	International Conference on Nano-technology	Vienna, Austria	March	2005
9	Tribo-Metrology for CMP Process Control	CMP-MIC Conference	Fremont, CA	February	2005
10	Multi-Sensing Tribo-Micro/Nano-Metrology	International Conference on Industrial Tribology	Mumbai, India	December	2004
11	Multi-Sensing Micro/Nano-Metrology	MRS Fall Meeting	Boston, MA	December	2004
12	Multi-Sensing Micro/Nano-Metrology	AVS Annual Meeting	Anaheim, CA	November	2004
13	Tribo-Metrology of Skin	International Tribology Symposium	Xi'an, China	November	2004
14	Multi-Sensing Micro/Nano-Metrology	ASTM Symposium on Adhesion	Washington, DC	October	2004
15	Multi-Sensing Micro/Nano-Metrology	Japan Vacuum Society Conference	Tokyo, Japan	September	2004
16	Tribo-Metrology for CMP Materials Control	CMP Symposium	Lake Placid, NY	August	2004
17	Tribo-Metrology for Bioengineering	Society Experimental Mechanics Annual Congress	Costa Mesa, CA	June	2004
18	Tribo-Metrology for MEMS	Society Experimental Mechanics Annual Congress	Costa Mesa, CA	June	2004
19	Multi-Sensing Tribo-Micro/Nano-Metrology	STLE Annual Meeting	Toronto, Canada	May	2004
20	Multi-Sensing Tribo-Metrology of Coatings	Society of Vacuum Coaters Conference	Dallas, TX	April	2004
21	Tribo-Metrology for CMP Process Control	American Vacuum Society ICMI Conference	Santa Clara, CA	March	2004
22	Tribo-Metrology for CMP Process Control	CMP-MIC Conference	Los Angeles, CA	February	2004
23	Multi-Sensing Tribo-Metrology of Coatings	Adhesion Society Annual Meeting	Wilmington, NC	February	2004
24	Tribo-Metrology for MEMS CMP Process Control	Photonics West - Micromachining and Microfabrication	San Jose, CA	January	2004
25	Tribo-Metrology of Skin	ASME/STLE Tribology Conference	Point Vendra, FL	October	2003
26	Multi-Sensing Tribo-Metrology of Thin Films	IDEMA HDD Symposium	Tokyo, Japan	October	2003
27	Multi-Sensing Metrology of Polymers	Mechanics of Time-Dependent Materials	Lake Placid, NY	October	2003
28	Tribo-Metrology for CMP Materials Control	CMP-VMIC Conference	Los Angeles, CA	September	2003
29	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	New York, NY	May	2003
30	Multi-Sensing Tribo-Metrology of Advanced Materials	Adhesion Society Annual Meeting	Myrtle Beach, SC	February	2003
31	Multi-Sensing Tribo-Metrology of Advanced Materials	ASM International Santa Clara Valley Chapter	Sunnyvale, CA	January	2003
32	Tribo-Metrology for CMP Process Control	AVS CMP User Group Meeting	Sunnyvale, CA	September	2002
33	Multi-Sensing Tribo-Metrology of Advanced Materials	6th Chinese Tribology Conference	Lanzhou, China	August	2002
34	Multi-Sensing Tribo-Metrology of Advanced Materials	STLE Annual Meeting	Houston, TX	May	2002
35	Separation of Powders from Mail	1st Bioterrorism Mobilization Conf.	Seattle, WA	April	2002
36	Multi-Sensing Tribo-Micro/Nano-Metrology	SPIE Internat. Sympos. On Micromachining	San Francisco, CA	October	2001
37	Multi-Sensing Tribo-Metrology of Advanced Materials	World Tribology Congress	Vienna, Austria	September	2001
38	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	Orlando, FL	May	2001
39	Tribo-Metrology for Copper CMP Process Control	Internat. Sematech CMP Working Group Meeting	San Francisco, CA	April	2001



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

40	Durability Evaluation of Ultra-Thin Coatings	Diskon	Tokyo, Japan	April	2001
41	Tribological Bench-Top Evaluation of CMP Process	CMP-MIC Conference	Santa Clara, CA	March	2001
42	Quantitative Bench-Top Evaluation of CMP Process	AVS CMP User Group Meeting	Santa Clara, CA	December	2000
43	Durability Evaluation of Ultra-Thin Coatings	IDEMA Tribology Symposium	Tokyo, Japan	July	2000
44	Durability Evaluation of Ultra-Thin Coatings	IDEMA HDD Tribology Symposium	Longmont, CO	June	2000
45	Multi-Sensing Tribo-Metrology of Coatings	STLE Annual Meeting	Nashville, TN	May	2000
46	Tribo-Metrology of Thin Films and Coatings	STLE Annual Meeting	Las Vegas, NV	May	1999
47	Tribo-Metrology of Thin Films and Coatings	STLE Northern California Section	Oakland, CA	January	1999
48	Metrology for Micro-Tribology	STLE Annual Meeting	Detroit, MI	May	1998
49	Tribo-Metrology for MEMS	NSF/ASME Workshop: Tribology Issues in MEMS	Columbus, OH	November	1997
50	Multi-Sensing Tribo-Metrology of Coatings	World Tribology Congress	London, England	September	1997
51	Metrology for Micro-Tribology	MIPE	Tokyo, Japan	July	1997
52	Multi-Sensing Tribo-Metrology of Lubricants	STLE Annual Meeting	Kansas City	May	1997
53	Tribology of Near-Contact Head-Disk Interface	Diskon	Tokyo, Japan	April	1997
54	Metrology for Micro-Tribology	IDEMA Tribology Symposium	San Jose, CA	May	1996
55	Micro-Tribology of Magnetic Head-Disk Interface	International Tribology Conference	Yokohama, Japan	October	1995
56	Tribology of Near-Contact Head-Disk Interface	6th Intern. Conf. on Magnetic Recording Media	Oxford, England	July	1995
57	Metrology for Micro-Tribology	STLE Northern California Section	Oakland, CA	March	1995
58	Tribology of Near-Contact Head-Disk Interface	Golden Gate Materials Conference	San Francisco, CA	February	1995
59	Tribology of Near-Contact Head-Disk Interface	ASME Energy Conference	New Orleans, LA	November	1994
60	Tribology of Near-Contact Head-Disk Interface	ASME/STLE Tribology Conference	Honolulu, HI	October	1994
61	Tribology of Near-Contact Head-Disk Interface	National Storage Information Consortium Meeting	Honolulu, HI	October	1994
62	Tribology of Near-Contact Head-Disk Interface	Diskon	San Jose, CA	September	1994
63	Nature of Friction and Frictional Auto-Oscillations	STLE Annual Meeting	Pittsburgh, PA	May	1994
64	Nature of Friction and Frictional Auto-Oscillations	World Tribology Congress	Budapest, Hungary	August	1993
65	Micro-Tribology of Magnetic Head-Disk Interface	MIT Tribology Symposium	Cambridge, MA	July	1993
66	Micro-Tribology of Magnetic Head-Disk Interface	National Storage Information Consortium Meeting	San Jose, CA	May	1993
67	Nature of Friction and Frictional Auto-Oscillations	STLE Annual Meeting	Calgary, Canada	May	1993
68	Micro-Tribology of Magnetic Head-Disk Interface	ASME Winter Annual Meeting	Anaheim, CA	November	1992
69	Micro-Tribology of Magnetic Head-Disk Interface	1st International Workshop on Microtribology	Morioka, Japan	October	1992
70	Nature of Friction and Frictional Auto-Oscillations	ASME/STLE Tribology Conference	Toronto, Canada	October	1990
71	Optimization of Boundary Lubrication Regime	International Tribology Conference	Tashkent, Uzbekistan	May	1985
72	Tribo-Metrology of Lubricants	Wear in Machines Tribology Conference	Bryansk, Russia	May	1985
73	Tribo-Metrology of Lubricants	Wear Problems in Engineering	Leningrad, Russia	September	1982
74	Evaluation of Durability of Spur Gears	Wear in Machines Tribology Conference	Bryansk, Russia	May	1977

**Universities and Academic Centers**

1	Latest Achievements in Tribo-Metrology	Indian Institute of Technology	Mumbai, India	January	2006
2	Latest Achievements in Tribo-Metrology	University of Genova	Genova, Italy	June	2005
3	Latest Achievements in Tribo-Metrology	University of Hannover	Hannover, Germany	March	2005
4	Tribo-Metrology of Thin Films and Nano-Coatings	BAM	Berlin, Germany	March	2005
5	Tribo-Metrology of Thin Films and Nano-Coatings	University of Modena	Modena, Italy	March	2005
6	Latest Achievements in Tribo-Metrology	BEM Engineering College	Bangalore, India	December	2004
7	Latest Achievements in Tribo-Metrology	India Institute of Technology	Delhi, India	December	2004
8	Latest Achievements in Tribo-Metrology	Hong Kong Polytechnic University	Hong Kong, China	October	2004
9	Latest Achievements in Tribo-Metrology	City University of Hong Kong	Hong Kong, China	October	2004
10	Latest Achievements in Tribo-Metrology	University of Wisconsin	Milwaukee, WI	August	2004
11	Tribo-Metrology of Thin Films and Nano-Coatings	University of Illinois	Chicago, IL	August	2004



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

12	Latest Achievements in Tribo-Metrology	Argonne National Laboratory	Argonne, IL	July	2004
13	Latest Achievements in Tribo-Metrology	Shanghai Jiao Tong University	Shanghai, China	March	2004
14	Tribo-Metrology of Thin Films and Nano-Coatings	North Carolina State University	Raleigh, NC	February	2004
15	Tribo-Metrology of Thin Films and Nano-Coatings	North Carolina A&T State University	Greenboro, NC	February	2004
16	Tribo-Metrology of CMP Process and Materials	International Microelectronics Consortium	Leuven, Belgium	February	2004
17	Tribo-Metrology of CMP Process and Materials	Shanghai Institute of Microsystem and Info Technology	Shanghai, China	December	2003
18	Tribo-Metrology of Thin Films and Nano-Coatings	Shanghai University	Shanghai, China	December	2003
19	Tribo-Metrology of CMP Process and Materials	Hebei Semiconductor Research Institute	Shijiazhuang, China	December	2003
20	Tribo-Metrology of CMP Process and Materials	Dalian University of Technology	Dalian, China	December	2003
21	Latest Achievements in Tribo-Metrology	Wuhan Research Institute of Materials Protection	Wuhan, China	December	2003
22	Tribo-Metrology of Thin Films and Nano-Coatings	University of Central Florida	Olando, FL	October	2003
23	Tribo-Metrology of CMP Process and Materials	Rensselaer Polytechnic Institute	Troy, NY	October	2003
24	Tribo-Metrology of Thin Films and Nano-Coatings	McGill University	Montreal, Canada	October	2003
25	Latest Achievements in Tribo-Metrology	University of Leoben	Leoben, Austria	June	2003
26	Latest Achievements in Tribo-Metrology	Vienna Technical University	Vienna, Austria	June	2003
27	Latest Achievements in Tribo-Metrology	Istanbul Technical University	Istanbul, Turkey	June	2003
28	Latest Achievements in Tribo-Metrology	University of North Carolina	Charlotte, NC	February	2003
29	Latest Achievements in Tribo-Metrology	Hunan University	Changsha, China	January	2003
30	Latest Achievements in Tribo-Metrology	Shanghai University	Shanghai, China	January	2003
31	Latest Achievements in Tribology and its Applications	Shanghai Jiao Tong University	Shanghai, China	January	2003
32	Tribo-Metrology of Lubricants and Coatings	DaLian Maritime University	Dalian, China	September	2002
33	Latest Achievements in Tribology and its Applications	JiLin University	Changchun, China	August	2002
34	Latest Achievements in Tribology and its Applications	Lanzhou Institute of Chemical Physics	Lanzhou, China	April	2002
35	Latest Achievements in Tribology and its Applications	Tsinghua University	Beijing, China	March	2002
36	Latest Achievements in Tribology and its Applications	University of South Florida	Tempe, FL	November	2000
37	Tribo-Metrology of Thin Films and Hard Coatings	State University of New York	Stony Brook, NY	January	2000
38	Tribo-Metrology of Thin Films and Soft Coatings	State University of New York	Syracuse, NY	January	2000
39	Tribo-Metrology of Thin Films and Coatings	University of California	Irvine, CA	December	1999
40	Tribo-Metrology of Thin Films and Coatings	California Institute of Technology	Pasadena, CA	September	1999
41	Tribology of Near-Contact Head-Disk Interface	Data Storage Institute	Singapore	June	1998
42	Tribology of Near-Contact Head-Disk Interface	University of California	San Diego, CA	January	1997
43	Advanced Tribology of Magnetic Head-Disk Interface	Santa Clara University	Santa Clara, CA	July - August	1996
44	Advanced Tribology of Magnetic Head-Disk Interface	Santa Clara University	Santa Clara, CA	Septem - Decem	1995
45	Tribology of Near-Contact Head-Disk Interface	University of California	Santa Barbara, CA	June	1992
46	Tribology of Near-Contact Head-Disk Interface	University of California	San Diego, CA	May	1992
47	Latest Achievements in Tribology and its Applications	Georgia Institute of Technology	Atlanta, GA	June	1989
48	Latest Achievements in Tribology and its Applications	Massachussetts Institute of Technology	Cambridge, MA	May	1989
49	Nature of Friction and Frictional Auto-Oscillations	Academic Institute for Applied Mechanics	Moscow, Russia	June	1986
50	Nature of Friction and Frictional Auto-Oscillations	Academic Institute for Machine Sciences	Moscow, Russia	April	1986
51	Friction Optimization in Boundary Lubrication	Academic Institute for Machine Sciences	Moscow, Russia	September	1983
52	Friction Optimization in Boundary Lubrication	Academic Institute for Applied Mechanics	Moscow, Russia	May	1983
53	Friction Optimization in Boundary Lubrication	Bryansk Polytechnic University	Bryansk, Russia	May	1983
54	Friction Optimization in Boundary Lubrication	Soviet Institute for Machinery Standardization	Moscow, Russia	April	1983
55	Friction Optimization in Boundary Lubrication	Leningrad Institute for Precision Mechanics & Optics	Leningrad, Russia	March	1983

# **EXHIBIT 3 – Part 7 of 7**



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue

Campbell, CA 95008, USA

Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

56	Friction Optimization in Boundary Lubrication	Leningrad Polytechnic University	Leningrad, Russia	March	1983
57	Friction Optimization in Boundary Lubrication	Academic Institute for Hard Materials and Coatings	Kiev, Ukraine	September	1982
<b>Corporations</b>					
1	Tribo-Metrology of Thin Films and Coatings	Bharat Heavy Electric	Hyderabad, CA	February	2006
2	Tribo-Metrology of Lubricants	Bharat Petroleum	Mumbai, India	January	2006
3	Tribo-Metrology of Thin Films and Coatings	Western Digital	Fremont, CA	August	2005
4	Tribo-Metrology of Metalworking Fluids and Lubricants	Ecolab	St. Paul, MN	August	2005
5	Latest Achievements in Tribo-Metrology	Salzgitter Mannesman	Salzgitter, Germany	June	2005
6	Latest Achievements in Tribo-Metrology	INA/FAG	Herzogenaurach, Germany	June	2005
7	Latest Achievements in Tribo-Metrology	German Institute for Rubber Technology	Hanover, Germany	June	2005
8	Latest Achievements in Tribo-Metrology	Volvo Technology	Goteburg, Sweden	June	2005
9	Latest Achievements in Tribo-Metrology	IWIS	Munich, Germany	March	2005
10	Tribo-Metrology of Chemical-Mechanical Polishing	Wacker	Burghausen, Germany	March	2005
11	Tribo-Metrology of Chemical-Mechanical Polishing	Infineon	Dresden, Germany	March	2005
12	Tribo-Metrology of Chemical-Mechanical Polishing	STMicroelectronics	Agrate, Italy	March	2005
13	Latest Achievements in Tribo-Metrology	India Oil Corporation	Fahdarabad, India	December	2004
14	Latest Achievements in Tribo-Metrology	Powder Metallurgy R&D Center	Hyderabad, India	December	2004
15	Latest Achievements in Tribo-Metrology	GE Welch R&D Center	Bangalore, India	December	2004
16	Tribo-Metrology of Thin Films and Coatings	Hind HiVacuum	Bangalore, India	December	2004
17	Latest Achievements in Tribo-Metrology	Saint-Gobain Advanced Materials	Northboro, MA	December	2004
18	Tribo-Metrology of Thin Films and Coatings	SAE Magnetics	Hong Kong	October	2004
19	Tribo-Metrology of Biomedical Materials and Devices	Guidant	St. Paul, MN	October	2004
20	Tribo-Metrology of Biomedical Materials and Devices	Medtronic	Minneapolis, MN	October	2004
21	Tribo-Metrology of Chemical-Mechanical Polishing	Matsushita Electric	Toyama, Japan	September	2004
22	Multi-Sensing Tribo-Micro/Nano-Metrology	Yamaha	Hamamatsu, Japan	September	2004
23	Latest Achievements in Tribo-Metrology	Eagle Industry	Tsukuba, Japan	September	2004
24	Tribo-Metrology of Chemical-Mechanical Polishing	Micron Technology	Boise, ID	September	2004
25	Tribo-Metrology of Chemical-Mechanical Polishing	LSI Logic	Gresham, OR	September	2004
26	Tribo-Metrology of Chemical-Mechanical Polishing	Namiki	Tokyo, Japan	August	2004
27	Tribo-Metrology of Chemical-Mechanical Polishing	Hitachi Chemical	Ibaraki, Japan	August	2004
28	Latest Achievements in Tribo-Metrology	Caterpillar	Peoria, IL	July	2004
29	Tribo-Metrology of Chemical-Mechanical Polishing	Rohm & Haas	Newark, DE	May	2004
30	Tribo-Metrology of Chemical-Mechanical Polishing	Novellus	Chandler, AZ	April	2004
31	Latest Achievements in Tribo-Metrology	Baosteel	Shanghai, China	March	2004
32	Tribo-Metrology of Chemical-Mechanical Polishing	JSR Corporation	Yokkaichi, Japan	March	2004
33	Latest Achievements in Tribo-Metrology	Lord	Cary, NC	February	2004
34	Tribo-Metrology of Chemical-Mechanical Polishing	Hitachi	Tokyo, Japan	October	2003
35	Latest Achievements in Tribo-Metrology	Miba	Laakirchen, Austria	June	2003
36	Latest Achievements in Tribo-Metrology	Arcelik	Istanbul, Turkey	June	2003
37	Latest Achievements in Tribo-Metrology	Korea Testing Laboratory	Seoul, South Korea	May	2003
38	Tribo-Metrology of Chemical-Mechanical Polishing	Samsung Corning	Suwon, South Korea	May	2003
39	Tribo-Metrology of Chemical-Mechanical Polishing	Samsung Electronics	Yongin, South Korea	May	2003
40	Tribo-Metrology of Chemical-Mechanical Polishing	Hynics Semiconductors	Icheon, South Korea	May	2003
41	Latest Achievements in Tribo-Metrology	NASA Goddard Space Center	Greenbelt, MD	April	2003
42	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Albuquerque, NM	April	2003
43	Tribo-Metrology of Electrical Connectors	National Electrical Carbon	Greenville, SC	February	2003



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

44	Tribo-Metrology of Metalworking Fluids and Lubricants	Lubrizol	Spartanburg, SC	February	2003
45	Tribo-Metrology of Electrical Connectors	Morganite	Dunn, NC	February	2003
46	Tribo-Metrology of Biomedical Materials and Skin	Unilever	Edgewater, NJ	January	2003
47	Latest Achievements in Tribo-Metrology	Aerospace Research # 4	Hohhot, China	January	2003
48	Tribo-Metrology of Polymers and Elastomers	Shanghai Polymer Research Center	Shanghai, China	January	2003
49	Tribo-Metrology of Biomedical Devices and Materials	DePuy Orthopedics	Warsaw, IN	November	2002
50	Tribo-Metrology of Chemical-Mechanical Polishing	Cabot Microelectronics	Aurora, IL	November	2002
51	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Roseville, CA	November	2002
52	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Santa Clara, CA	October	2002
53	Tribo-Metrology of Chemical-Mechanical Polishing	Strasbaugh	San Luis Obispo, CA	August	2002
54	Tribo-Metrology of Chemical-Mechanical Polishing	SpeedFam-IPEC	Chandler, AZ	August	2002
55	Tribo-Metrology of Lubricants and Coatings	1st Chinese Automobile Company	Changchun, China	August	2002
56	Tribo-Metrology of Biomedical Materials and Skin	Procter & Gamble	Cincinnati, OH	June	2002
57	Tribo-Metrology of Chemical-Mechanical Polishing	Rodel	Phoenix, AZ	April	2002
58	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Shanghai, China	March	2002
59	Tribo-Metrology of Biomedical Devices and Materials	Guidant	Menlo Park, CA	March	2002
60	Tribo-Metrology of Polymers and Elastomers	Advanced Elastomer Systems	Akron, OH	January	2002
61	Latest Achievements in Tribo-Metrology	NASA Glenn Research Center	Cleveland, OH	January	2002
62	Tribo-Metrology of Metalworking Fluids and Lubricants	Milacron	Cincinnati, OH	January	2002
63	Tribo-Metrology of Sliding and Rolling Bearings	Timken	Canton, OH	January	2002
64	Tribo-Metrology of Chemical-Mechanical Polishing	IBM Semiconductors	Fishkill, NY	October	2001
65	Tribo-Metrology of Chemical-Mechanical Polishing	IBM Watson Research Center	Yorktown Heights, NY	October	2001
66	Tribo-Metrology of Lubricants and Coatings	Ecolab	St. Paul, MN	June	2001
67	Tribo-Metrology of Biomedical Devices and Materials	St. Jude Medical	St. Paul, MN	June	2001
68	Tribo-Metrology of Chemical-Mechanical Polishing	Intel	Hillsboro, OR	May	2001
69	Tribo-Metrology of Chemical-Mechanical Polishing	Cabot Microelectronics	Aurora, IL	February	2001
70	Tribo-Metrology of Chemical-Mechanical Polishing	Ebara	Fujisawa, Japan	February	2001
71	Tribo-Metrology of Chemical-Mechanical Polishing	Toshiba	Shizuoka, Japan	February	2001
72	Tribo-Metrology of Chemical-Mechanical Polishing	Sony	Kanagawa, Japan	January	2001
73	Tribo-Metrology of Chemical-Mechanical Polishing	LSI Logic	Ibaraki, Japan	January	2001
74	Tribo-Metrology of Chemical-Mechanical Polishing	NEC	Kanagawa, Japan	January	2001
75	Tribo-Metrology of Chemical-Mechanical Polishing	Greene, Tweed & Company	Kulpsville, PA	December	2000
76	Tribo-Metrology of Chemical-Mechanical Polishing	Rodel	Newark, DE	December	2000
77	Tribo-Metrology of Biomedical Devices and Materials	United States Surgical	North Haven, CT	December	2000
78	Latest Achievements in Tribo-Metrology	International Sematech	Austin, TX	November	2000
79	Tribo-Metrology of Sliding and Rolling Bearings	SKF	Utrecht, Netherlands	September	2000
80	Tribo-Metrology of Chemical-Mechanical Polishing	SpeedFam-IPEC	Chandler, AZ	August	2000
81	Tribo-Metrology of Lubricants and Coatings	Honeywell Aerospace	Tempe, AZ	August	2000
82	Latest Achievements in Tribo-Metrology	Fuji Electric	Nagano, Japan	July	2000
83	Latest Achievements in Tribo-Metrology	Sony	Sendai, Japan	July	2000
84	Latest Achievements in Tribo-Metrology	Mitsubishi Chemical	Mizushima, Japan	July	2000
85	Latest Achievements in Tribo-Metrology	Hitachi	Ibaraki, Japan	July	2000
86	Tribo-Metrology of Lubricants and Coatings	Verbatim	San Diego, CA	April	2000
87	Tribo-Metrology of Biomedical Devices and Materials	Orthopaedic Research Center	Los Angeles, CA	April	2000
88	Latest Achievements in Tribo-Metrology	3M	St. Paul, MN	February	2000
89	Latest Achievements in Tribo-Metrology	Imation	Oakdale, MN	February	2000



**CETR Confidential**

**CENTER FOR TRIBOLOGY, INC.**  
 1715 Dell Avenue  
 Campbell, CA 95008, USA  
 Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

90	Tribo-Metrology of Lubricants	Cargill	Minneapolis, MN	February	2000
91	Tribo-Metrology for Biomedical Devices	SurModics	St. Paul, MN	February	2000
92	Tribo-Metrology of Thin Films and Coatings	Essilor	Paris, France	January	2000
93	Tribo-Metrology of Thin Films and Coatings	Balzars	Liechtenstein	January	2000
94	Tribo-Metrology of Lubricants and Coatings	DuPont	Wilmington, DE	January	2000
95	Tribo-Metrology of Thin Films and Coatings	US Army Benet Lab	Watervliet, NY	January	2000
96	Tribo-Metrology of Thin Films and Coatings	Sulzer Metco	Westbury, NY	January	2000
97	Tribo-Metrology of Thin Films and Coatings	Gillette	Boston, MA	January	2000
98	Latest Achievements in Tribo-Metrology	Rodel	Newark, DE	January	2000
99	Latest Achievements in Tribo-Metrology	YTC America	Camarillo, CA	December	1999
100	Tribo-Metrology of Thin Films and Coatings	Imation	Camarillo, CA	December	1999
101	Tribo-Metrology of Lubricants	Castrol Industrial	Downers Grove, IL	October	1999
102	Tribo-Metrology of Thin Films and Coatings	Honeywell Aerospace	Torrance, CA	September	1999
103	Latest Achievements in Tribo-Metrology	Jet Propulsion Laboratory	Pasadena, CA	September	1999
104	Tribo-Metrology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	April	1999
105	Tribo-Metrology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	April	1999
106	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Kawasaki, Japan	April	1999
107	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Yokohama, Japan	April	1999
108	Tribo-Metrology of Magnetic Head-Disk Interface	Showa Denko	Chiba, Japan	April	1999
109	Tribo-Metrology of Magnetic Head-Disk Interface	NEC	Kanagawa, Japan	April	1999
110	Tribo-Metrology of Magnetic Head-Disk Interface	Yamaha	Hamamatsu, Japan	April	1999
111	Latest Achievements in Tribo-Metrology	Hewlett Packard	Vancouver, WA	March	1999
112	Latest Achievements in Tribo-Metrology	FormFactor	Livermore, CA	January	1999
113	Tribo-Metrology of Thin Films and Coatings	Iomega	Roy, UT	December	1998
114	Tribo-Metrology of Lubricants	Castrol Industrial	Chicago, IL	December	1998
115	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Longmont, CO	September	1998
116	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Bloomington, MN	September	1998
117	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Kawasaki, Japan	September	1998
118	Tribo-Metrology of Magnetic Head-Disk Interface	Sony	Shinagawa, Japan	September	1998
119	Tribo-Metrology of Magnetic Head-Disk Interface	Read-Rite Sumitomo	Osaka, Japan	September	1998
120	Tribo-Metrology of Magnetic Head-Disk Interface	Sharp	Yokohama, Japan	September	1998
121	Tribo-Metrology of Magnetic Head-Disk Interface	Fuji Electric	Nagano, Japan	September	1998
122	Tribo-Metrology of Magnetic Head-Disk Interface	SilMag	Grenoble, France	June	1998
123	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Singapore	June	1998
124	Tribo-Metrology of Magnetic Head-Disk Interface	Hoya	Singapore	June	1998
125	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Singapore	June	1998
126	Testing and Analysis of Magnetic Disk Drives	Hitachi	Santa Clara, CA	May	1998
127	Tribo-Metrology of Magnetic Head-Disk Interface	Iomega	San Diego, CA	March	1998
128	Latest Achievements in Tribo-Metrology	Dana Corporation	Ottawa Lake, OH	November	1997
129	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Clonmel, Ireland	September	1997
130	Tribo-Metrology of Magnetic Head-Disk Interface	Trace Storage	Hsinchu, Taiwan	July	1997
131	Tribo-Metrology of Magnetic Head-Disk Interface	SAE Magnetics	Hong Kong	July	1997
132	Tribo-Metrology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	July	1997
133	Tribo-Metrology of Magnetic Head-Disk Interface	Iomega	Roy, UT	May	1997
134	Tribo-Metrology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	April	1997
135	Tribo-Metrology of Magnetic Head-Disk Interface	Fujitsu	Atsugi, Japan	April	1997
136	Tribo-Metrology of Magnetic Head-Disk Interface	Fuji Electric	Nagano, Japan	April	1997
137	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Mizushima, Japan	April	1997
138	Tribo-Metrology of Magnetic Head-Disk Interface	IBM Almaden Research Center	San Jose, CA	February	1997
139	Tribo-Metrology of Magnetic Head-Disk Interface	Trace Storage	Hsinchu, Taiwan	January	1997



**CETR Confidential****CENTER FOR TRIBOLOGY, INC.**

1715 Dell Avenue  
Campbell, CA 95008, USA  
Tel: (408) 376-4040 • Fax: (408) 376-4050 • [www.cetr.com](http://www.cetr.com)

140	Testing and Analysis of Magnetic Disk Drives	Toshiba	Irvine, CA	November	1996
141	Testing and Analysis of Magnetic Disk Drives	Hitachi	Brisbane, CA	August	1996
142	Testing and Analysis of Magnetic Disk Drives	Dell Computer	Austin, TX	August	1996
143	Tribo-Metrology of Magnetic Head-Disk Interface	Samsung	Korea	July	1996
144	Tribo-Metrology of Magnetic Head-Disk Interface	Hyundai	Korea	July	1996
145	Tribo-Metrology of Magnetic Head-Disk Interface	Hoya	Singapore	April	1996
146	Tribo-Metrology of Magnetic Head-Disk Interface	Seagate Technology	Singapore	April	1996
147	Tribo-Metrology of Magnetic Head-Disk Interface	Mitsubishi Chemical	Singapore	April	1996
148	Tribo-Metrology of Magnetic Head-Disk Interface	Akashic Memories	San Jose, CA	December	1995
149	Advanced Tribology of Magnetic Head-Disk Interface	Seagate Technology	Bangkok, Thailand	November	1995
150	Advanced Tribology of Magnetic Head-Disk Interface	Hitachi	Odawara, Japan	November	1995
151	Advanced Tribology of Magnetic Head-Disk Interface	Matsushita Electric	Osaka, Japan	November	1995
152	Advanced Tribology of Magnetic Head-Disk Interface	Apple Computer	Cupertino, CA	July	1995
153	Testing and Analysis of Magnetic Disk Drives	MTI	Anaheim, CA	May	1995
154	Micro-Tribology of Magnetic Head-Disk Interface	Corning Inc.	Corning, NY	April	1995
155	Micro-Tribology of Magnetic Head-Disk Interface	NTT	Tokyo, Japan	April	1995
156	Micro-Tribology of Magnetic Head-Disk Interface	NEC	Kanagawa, Japan	April	1995
157	Micro-Tribology of Magnetic Head-Disk Interface	Fuji Electric	Kanagawa, Japan	April	1995
158	Micro-Tribology of Magnetic Head-Disk Interface	Fujitsu	Atsugi, Japan	April	1995
159	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Oklahoma City, OK	February	1995
160	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Scotts Valley, CA	January	1995
161	Micro-Tribology of Magnetic Head-Disk Interface	Seagate Technology	Oklahoma City, OK	December	1994
162	Micro-Tribology of Magnetic Head-Disk Interface	Corning Inc.	Corning, NY	November	1994
163	Micro-Tribology of Magnetic Head-Disk Interface	Quantum	Milpitas, CA	November	1994
164	Micro-Tribology of Magnetic Head-Disk Interface	Samsung	San Jose, CA	April	1994
165	Micro-Tribology of Magnetic Head-Disk Interface	Censtor	San Jose, CA	November	1993
166	Micro-Tribology of Magnetic Head-Disk Interface	StorMedia	Santa Clara, CA	October	1993
167	Micro-Tribology of Magnetic Head-Disk Interface	Showa Denko	Chiba, Japan	August	1993
168	Tribology of Near-Contact Head-Disk Interface	Maxtor	Longmont, CO	February	1993
169	Tribology of Near-Contact Head-Disk Interface	Hutchinson Technology	Hutchinson, MN	August	1992
170	Tribology of Near-Contact Head-Disk Interface	Maxtor	San Jose, CA	November	1992
171	Tribology of Near-Contact Head-Disk Interface	Showa Denko	Chiba, Japan	October	1992
172	Tribology of Near-Contact Head-Disk Interface	Yamaha	Hamamatsu, Japan	October	1992
173	Advanced Tribology of Magnetic Head-Disk Interface	Read-Rite	Milpitas, CA	February	1992
174	Stiction Phenomenon in Head-Disk Interface	IBM Storage Systems	San Jose, CA	April	1991
175	Advanced Tribology of Magnetic Head-Tape Interface	IBM Storage Systems	Tucson, AZ	April	1990
176	Latest Achievements in Tribology and its Applications	IBM Almaden Research Center	San Jose, CA	May	1989
177	Latest Achievements in Tribology and its Applications	IBM Storage Systems	San Jose, CA	May	1989
178	Friction Optimization in Boundary Lubrication	Moscow Center for Machine Tools and Robotics	Moscow, Russia	March	1986
179	Friction Optimization in Boundary Lubrication	Leningrad Machine Tool Company	Leningrad, Russia	November	1985
180	Durability Evaluation of Spur Gears	Odessa Machine Tool Company	Odessa, Ukraine	June	1981

# **EXHIBIT 4**



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.  
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.  
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

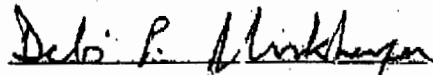
**RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE**  
**CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446**  
**AND OTHER MATTERS**

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

## I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together "Defendants") to review U.S. Patent No. 5,314,446 ("the '446 patent"), its prosecution history, the Expert Report of Dr. David Brookstein ("Brookstein Report"), reports prepared by the Center for Tribology, Inc., as well as by Dr. Robert Burks, and certain other materials, and to provide my opinion on issues raised by Dr. Brookstein's report, including: i) whether a person of ordinary skill in the art in February 1992 would have understood the term "PE," as described and claimed in the '446 patent, to include ultra high molecular weight polyethylene ("UHMWPE"); ii) what a person of ordinary skill in the art in February 1992 would have understood to be the basic and novel characteristics of the invention described and claimed in the '446 patent; iii) whether the addition of a coating, as used on Arthrex's FiberWire sutures, affects those basic and novel characteristics; iv) whether the addition of nylon, as used in Arthrex's TigerWire sutures, affects those basic and novel characteristics; v) whether the addition of an adhesive, as used on Arthrex's FiberStick sutures, affects those basic and novel characteristics, vi) whether the braids produced by Pearsalls are suitable for uses other than FiberWire suture; and vii) whether claim 9 of the '446 patent, which I understand has been newly asserted by DePuy Mitek, is invalid in view of prior art. I am being compensated at a rate of \$1000.00 per day.

Dated: March 24, 2006

  
Debi Prasad Mukherjee, Sc/D.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent Nos. 5,314,446 and other matters was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 24th day of March 2006:

Lynn A. Malinoski  
Woodcock Washburn, LLP  
One Liberty Place, 46th Floor  
Philadelphia, PA. 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

Daniel J. Gleason  
Nutter McClennan & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2604  
Telephone: (617) 439-2000  
Facsimile: (617) 310-9000

\_\_\_\_\_  
s/Salvatore P. Tamburo



# **EXHIBIT 5**



PHILADELPHIA OFFICE  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

---

ERICH M. FALKE  
215-557-5926  
falke@woodcock.com

March 28, 2006

Charles Saber, Esquire  
Dickstein Shapiro Morin & Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc.**  
**Case No. 04-12457 PBS**

Dear Chuck:

We received the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters" ("the Report"). Unfortunately, there are many issues that need to be resolved before Mitek's experts can fully respond to the Report. Please produce the following information by this Friday (March 31), so that Mitek's experts can evaluate this information in advance of April 7th:

(1) a sample of suitable length of each of the coated and uncoated sutures (as sterilized by Sterile Systems) referenced in Section 3 of Ex. 20 of the Report;

(2) documents and communications between the Center for Tribology, Inc. ("CETR") and (i) Arthrex; (ii) Dr. Mukherjee; or (iii) Dickstein Shapiro Morin & Oshinsky concerning any aspect of Ex. 20 to the Report, including, but not limited to, documents concerning the "suggestions of the law firm" as noted on p. 2 of Ex. 20 of the Report;

(3) Arthrex's and Dr. Mukherjee's documents concerning CETR including, but not limited to, all documents showing the relationship between them;

(4) CETR documents that relate to this case including, communications, documents related to any testing performed, any tests and test results not reported, documents describing the testing protocols;

(5) documents and files from Dr. Norm Gitis, Mr. Michael Vinogradov, Sterile Systems, AMER (including, but not limited to, Tony Lin) that relate to this case;

(6) documents that describe the samples tested including Arthrex and Pearsalls documentation (e.g., "DT sheets," manufacturing specifications, invoices, purchase orders);

(7) a copy of each of the references listed on page 17 of Ex. 20 of the Report; and



Charles Saber, Esquire  
March 28, 2006  
Page 2

(8) documents sufficient to describe the sterilization specifications used to sterilize the suture samples.

Also, please advise whether your firm represents any of the following entities or people and if so, when they are available for deposition. Mitek's expert cannot fully respond to Dr. Mukherjee's report without the benefit of these depositions.

(1) The person from Pearsalls who manufactured the samples, took them from the manufacturing line, and sent them to Arthrex.

(2) The person who ordered the samples from Pearsalls.

(3) Each CETR person involved in designing and performing tests outlined in Ex. 20 of the Report.

(4) Each person that handled the tested sutures at Sterile Systems and performed the sterilization.

(5) Each person that handled the tested sutures from AMER and each person from AMER who performed work related to this case.

As Mitek will not be able to take depositions before April 7<sup>th</sup>, Mitek's experts can only respond on April 7<sup>th</sup> based on the information that is available to them. If Arthrex will not provide this information, please explain Arthrex's reasons for not providing it. If formal subpoenas are needed, please advise. Also, please be advised that there may be other information that Mitek's experts will need.

Additionally, Mitek believes Arthrex improperly marked Ex. 20 of the Report as "Confidential: Non-Patent Prosecution Counsel Only." Please provide your reasons for marking it with such a designation.

Sincerely,

  
Erich M. Falke

EMF/td

# **EXHIBIT 6**





**PHILADELPHIA OFFICE**  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

**ERICH M. FALKE**  
215-557-5926  
falke@woodcock.com

March 30, 2006

Charles Saber, Esquire  
Dickstein Shapiro Morin & Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc.**  
**Case No. 04-12457 PBS**

Dear Chuck:

Please let me know if we will be receiving, by March 31, the information requested in my March 28 letter so that our expert can potentially respond by the April 7 deadline.

Sincerely,

Erich M. Falke

EMF/td

# **EXHIBIT 7**



PHILADELPHIA OFFICE  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

ERICH M. FALKE  
215-557-5926  
falke@woodcock.com

April 4, 2006

Charles Saber, Esquire  
Dickstein Shapiro Morin & Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc.**  
**Case No. 04-12457 PBS**

Dear Chuck:

This letter confirms our telephone discussion of Friday, March 31 in which we discussed my March 28<sup>th</sup>, 30<sup>th</sup>, and March 31<sup>st</sup> letters.

You represented that no untested CETR suture samples exist, other than 2 cm, which you explained was insufficient for testing. You also stated that you were not aware of whether any of the samples tested by CETR exist. But you represented that you would follow up with CETR and provide us with any existing samples. Please let us know immediately if any samples exist. If samples exist, please produce them immediately with information sufficient to describe whether they are tested or untested samples and the samples' origin. If no samples exist, please explain what CETR did with the tested and untested suture samples.

We discussed the documents that we had requested. You represented that you are checking to determine whether documents exist in the following areas:

documents between CETR and (i) Arthrex; (ii) Dr. Mukherjee; or (iii) Dickstein Shapiro Morin & Oshinsky concerning any aspect of Ex. 20 to the Report, including, but not limited to, documents concerning the "suggestions of the law firm" as noted on p. 2 of Ex. 20 of the Report;

CETR documents that relate to this case including, communications, documents related to any testing performed, any test results or test data (including data recorded by machine or humans, and data not reported by CETR) and detailed testing procedures;

documents that describe the samples tested including Arthrex and Pearsalls documentation of the samples (e.g., "DT sheets," manufacturing specifications, invoices, purchase orders);



Charles Saber, Esquire  
April 4, 2006  
Page 2

documents sufficient to describe the sterilization specifications used to sterilize the suture samples; and

documents describing the origin and explanation of the samples produced after the close of fact discovery on about February 7, 2006.

Also, you represented that you are "considering" whether to provide us with the requested deposition of the Pearsalls employee who took the samples from the manufacturing line. As we explained, that deposition is necessary so that Mitek can understand exactly what sutures were tested by CETR. Mitek is entitled to this information, and we urge you to provide it. We requested a response by today at the latest. You have not responded.

Also, we sent you a letter describing certain unproduced Pearsalls' batch records referenced in Ex. 25 to Dr. Mukherjee's Responsive Report. When we spoke on Friday, you were not prepared to discuss this issue. We are still awaiting a response on this issue.

Mitek's experts cannot fully respond to Dr. Mukherjee's report without the benefit of this information. It is almost the close of business on Tuesday, leaving just 3 days before Mitek's experts are due to file their rebuttal reports, and you have not afforded them the opportunity to review the requested information. You ignored our letters of last week until Friday afternoon, and we still have not heard from you with respect to whether we will be receiving any of the requested information. Consequently, Mitek reserves the right to supplement its reports after it receives this information. We also reserve the right to seek the other information requested in our letters regarding Arthrex's expert reports.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Falke', with a long horizontal line extending to the right.

Erich M. Falke

EMF/td



# **EXHIBIT 8**



PHILADELPHIA OFFICE  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

ERICH M. FALKE  
215-557-5926  
falke@woodcock.com

April 10, 2006

Charles Saber, Esquire  
Dickstein Shapiro Morin & Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc.**  
**Case No. 04-12457 PBS**

Dear Chuck:

I am writing in response to your Friday evening email. You claim not to have been delaying in responding to our requests for discovery concerning Arthrex's and Pearsalls' rebuttal expert reports. But you have not responded to any of our discovery requests regarding Dr. Mukherjee's Responsive and Dr. Gitis' expert reports. You claim to be trying to determine what has been requested. But you have not raised any questions about the requests since we spoke on March 31, 2006. Further, your alleged confusion is really silly because the requests are pretty basic (e.g., all data generated during all tests, samples of what was tested, detailed testing procedures, communications among CETR and Dr. Mukherjee, and your firm, sterilization procedures, documents describing the tested samples and their chain of custody, documents or witnesses who can identify the samples produced after close of fact discovery).

Also, you have failed to advise whether you will be making fact witnesses available to testify regarding the samples which were made for CETR. As we have expressed on numerous occasions, Mitek wants to depose the Pearsalls fact witness, who has first hand knowledge of the identify of the tested samples, including their construction, what processing they underwent, and how they were handled.

Further, we want to depose the fact witness from the sterilization lab regarding the sterilization processes and the handling of the tested samples and the lab that took pictures of the samples. As we indicated, these depositions were not as high a priority given the limited time to prepare rebuttal reports.

It does not take any research to let us know whether you will be making fact witnesses available for deposition. We asked that you let us know about the Pearsalls fact witness by early last week, so that we could take that deposition before the responsive expert reports were served. We have not received a response. Please advise whether we should resolve the issues with respect to fact witnesses and documents by motions.



Charles Saber, Esquire  
April 10, 2006  
Page 2

At this point, you have not afforded Mitek's experts the opportunity of reviewing the requested information before preparing their rebuttal reports. We will be supplementing them once the requested information is produced and/or moving to exclude portions of Arthrex's and Pearsalls' expert reports.

Sincerely,

A handwritten signature in black ink, appearing to be 'E. Falke', written over a horizontal line.

Erich M. Falke

EMF/td

# **EXHIBIT 9**





**INTELLECTUAL PROPERTY LAW**  
ATLANTA • PHILADELPHIA • SEATTLE

**PHILADELPHIA OFFICE**  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

April 13, 2006

**ERICH M. FALKE**  
215-557-5926  
falke@woodcock.com

Charles Saber, Esquire  
Dickstein Shapiro Morin & Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc.**  
**Case No. 04-12457 PBS**

Dear Chuck:

You have not responded to any of our requests for discovery concerning Dr. Mukherjee's and Dr. Gitis' reports. We first made a request for certain information on March 28, 2006. It is now April 13th, the due date for rebuttal expert reports, and we have not received any of the requested information. Nor have you even indicated if Arthrex and Pearsalls will be producing the requested information.

On April 7, 2006, you claimed not to be "delaying," but we have not heard from you since that communication. Based on your lack of response since March 28, 2006, we understand that Arthrex and Pearsalls will not be producing the requested information. You appear to be engaging in the classic lawyer "I don't understand what you want" delay/obstruction tactic when the requests are straightforward. We discussed the requests on March 31, 2006, and you have not indicated any "confusion" since then. We will be addressing the issue by motion.

Sincerely,

Erich M. Falke

EMF/td

# **EXHIBIT 10**



**PHILADELPHIA OFFICE**  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215-568-3100  
Fax: 215-568-3439

May 31, 2006

---

**MICHAEL J. BONELLA**  
PHILADELPHIA OFFICE  
215-564-8987  
bonella@woodcock.com

*Via Email*  
Salvatroe Tamburo, Esq.  
Dickstein Shapiro Morin &  
Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc.**  
**Case No. 04-12457 PBS**

Dear Sal:

Thank you for your May 26, 2006 communication expert deposition scheduling. It appears that we have agreed on the following schedule (except Mr. O'Donnell), please confirm.

<b>Deponent</b>	<b>Date/Location</b>
Dr. Burks	6/7 Salt Lake City, Utah
Dr. Gering	6/7 Phil.
Dr. Mukherjee	6/13 D.C.
Dr. Bosco	6/15 D.C.
Mr. Witherspoon	6/20 D.C.
Dr. Gitis	6/21 D.C.
Dr. Hermes	6/27 Phil.
Mr. O'Donnell	6/16 or 6/19 Phil.
Pearsalls	6/30 U.K.



Salvatore Tamburo, Esq.  
May 31, 2006  
Page 2

### **Pearsalls' Depositions**

It is not clear whether the four fact witnesses that you have identified can authenticate and explain which manufacturing processes Pearsalls used to make the coated and uncoated samples that were tested by Dr. Gitis. We are requesting that Pearsalls produce fact witnesses that have first-hand knowledge of the processes that were used to make the specific samples that Dr. Gitis, Dr. Mukherjee, and Dr. Burks tested. We also believe that both Pearsalls & Arthrex have an obligation under Rule 26 to identify such witnesses.

Unfortunately, in advance of the depositions, we cannot commit to a time limit on the Pearsalls' depositions. But we will make every effort to keep them as brief as possible. Although it is possible that we may not need to depose all four witnesses, it is also possible that we may need to depose all of them. Again, while we make every effort to be as brief as possible and to limit who is deposed, we ask that you hold availability on July 1 (or start on 6/29), so that we can ensure that we can complete the depositions. Hopefully, that will not be necessary, but we want to make sure that there is sufficient time to complete the depositions.

We understand that Pearsalls & Arthrex refuse to answer the interrogatories. But if they do so, we may be able to shorten and avoid unnecessary depositions.

Are the witnesses available to be deposed in London? Also, please confirm the dates this week, so that we can book the airline tickets, which are somewhat limited.

Also, we have repeatedly requested documents that appear to be relevant to these depositions, such as the Pearsalls batch records for batch 28893, but we have not received them.

### **Dr. Gitis' Samples**

We are still requesting the entirety of what remains of what Dr. Gitis actually tested. We would like the samples now, so that our expert can consider them in preparing his supplemental report, and we can consider them before we depose Dr. Gitis. If you do not produce them until the deposition, it hinders our ability to ask questions at the deposition, which might result from an analysis of the samples. We would rather have the samples now, so that we can avoid any issue of having to reconvene the deposition to address issues raised by Mitek's experts' analysis of the samples after the deposition.





Salvatore Tamburo, Esq.  
May 31, 2006  
Page 3

**Dr. Brookstein's Deposition & Report**

We agree in principal to the dates that you have proposed with respect to Dr. Brookstein, but propose a slight adjustment in your proposed dates because there is not sufficient time for Dr. Brookstein to complete his report and the Markman hearing in the SlingShot case may be scheduled for July 6<sup>th</sup>. We propose that he serves his supplemental report on July 13<sup>th</sup> (this assumes that the Markman in the SlingShot case is moved) and is deposed on July 25<sup>th</sup>. We do, however, reserve the right to reconsider these dates if we have not received the requested information by then and/or there is not sufficient time for his to complete his analysis based on information that was requested, but not produced.

You raise the issue of why Dr. Brookstein will be supplementing his report. I do not wish to engage in an argument with you about this, but rather am just responding to your question. He will be supplementing based on a variety of information that was requested, but not produced before his rebuttal report was served. This includes but is not limited to Dr. Gitis' data, Pearsalls' documents, Dr. Gitis' documents, Pearsalls' depositions, and samples. Also, we still do not fully understand the tests that Dr. Gitis conducted (which is the reason for the repeated requests regarding procedures and equipment used by Dr. Gitis), so he will be supplementing based on his deposition and those documents (if they are produced). We disagree that Dr. Gitis' report explains his tests sufficiently so that they can be fully understood or replicated. That is why we have been requesting documents concerning the general machines and procedures that he used since March.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Bonella".

Michael J. Bonella

# **EXHIBIT 11**

D I C K S T E I N   S H A P I R O   M O R I N   &   O S H I N S K Y   L L P

2101 L Street NW • Washington, DC 20037-1526

Tel (202) 785-9700 • Fax (202) 887-0689

Writer's Direct Dial: (202) 822-5164

Writer's EMail: TamburoS@DSMO.com

May 2, 2006

**VIA FACSIMILE (215) 568-3439**

Michael J. Bonella, Esq.  
Woodcock Washburn LLP  
1 Liberty Place, 46th Floor  
Philadelphia, PA 19103

Re: DePuy Mitek, Inc. v. Arthrex, Inc.  
Case No. 04-12457 PBS

Dear Mike:

Based upon our recent discussions regarding Dr. Mukherjee's and Dr. Gitis' expert reports, and in light of the recent productions made by Arthrex, Pearsalls and CETR, Arthrex and Pearsalls respond to the balance of outstanding issues as follows:

We have received from CETR a small amount of what we believe to be both untested uncoated and coated FiberWire suture remaining from Dr. Gitis' testing. We will be sending you approximately 10 ft. of the uncoated material and approximately 3 ft. of the coated material by Fedex.

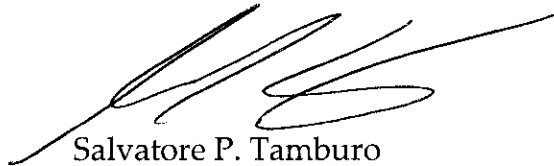
We have also received from CETR a small amount (a small baggie or so) of what we believe to be a mixture of coated and uncoated tested FiberWire suture. We cannot segregate these materials with certainty. We will, however, bring these materials to Dr. Gitis' deposition.

We have also received from CETR a CD containing Excel files of raw data gathered during testing of the coated and uncoated FiberWire sutures and as reflected in Dr. Gitis' expert report. We will send a copy of this CD to you by Fedex.

Michael J. Bonella, Esq.  
May 2, 2006  
Page Two

With regard to DePuy Mitek's request to depose Pearsalls personnel, we are informed that there were several persons at Pearsalls who may have had some involvement in the production and transport of the coated and uncoated FiberWire. Since we, of course, cannot anticipate the precise questions that you may ask, we will make these people available for depositions in Taunton at a mutually convenient time. As an alternative to depositions, we would also accept and respond to an interrogatory addressed to Pearsalls on this subject. Please let us know DePuy Mitek's availability for such depositions or whether you would prefer to proceed by interrogatory.

Very truly yours,

A handwritten signature in black ink, appearing to read "S. Tamburo", with a long horizontal flourish extending to the right.

Salvatore P. Tamburo

SPT/rrl

# **EXHIBIT 12**



D I C K S T E I N S H A P I R O M O R I N & O S H I N S K Y L L P

2101 L Street NW • Washington, DC 20037-1526

Tel (202) 785-9700 • Fax (202) 887-0689

Writer's Direct Dial: (202) 822-5164

Writer's EMail: TamburoS@DSMO.com

June 14, 2006

**VIA FEDEX**

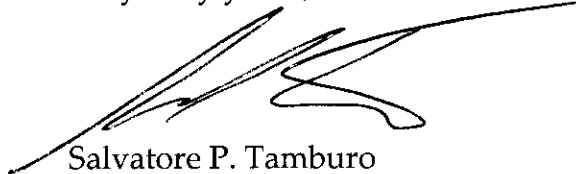
Michael J. Bonella, Esq.  
Woodcock Washburn LLP  
1 Liberty Place, 46th Floor  
Philadelphia, PA 19103

Re: DePuy Mitek, Inc. v. Arthrex, Inc.  
Case No. 04-12457 PBS

Dear Mike:

The enclosed documents (CETR 0076-79) are a supplement to Dr. Gitis' expert report served on March 24, 2006.

Very truly yours,

A handwritten signature in black ink, appearing to read 'S. Tamburo', with a long horizontal flourish extending to the right.

Salvatore P. Tamburo

SPT/rrl

# **EXHIBIT 13**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.,</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom,</b>	)	
	)	
<b>Defendants.</b>	)	

**Supplemental Expert Report of Dr. David Brookstein**

**I. Background Information**

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

**II. Summary of Opinions**

2. The samples tested by Dr. Gitis that he labeled “coated” and “uncoated” were manufactured differently. These manufacturing differences affect FiberWire’s UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire’s coating based on Dr. Gitis’ tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

3. It is my opinion that Dr. Gitis' testing methodology was not based on accepted scientific methods or he failed to provide information that showed that his tests and analysis were based on accepted scientific methods. Therefore, it is my opinion that his tests and data cannot be relied on to analyze the effects, if any, of FiberWire's coating on the suture's properties.

4. It is my opinion that no reliable conclusions can be made about the effect, if any, of FiberWire's coating on the suture's properties based on Arthrex's knot tie-down test because either the "coated" or "uncoated" samples were manufactured differently or it is not known how they were manufactured.

### **III. Dr. Gitis' Tests Are Scientifically Unreliable Because The Tested Samples Differed In How They Were Manufactured**

5. Dr. Gitis tested samples in which the only purported difference between the samples was that one set was "coated" and the other set was not. But the samples differed in more respects than just coating. Specifically, the "uncoated" sample was not heated and stretched, but the "coated" sample was heated and stretched twice, as is the case during the typical manufacturing of FiberWire sutures. Therefore, any conclusions that Dr. Mukherjee and Dr. Gitis made about the effect of a coating based on Dr. Gitis' tests are not reliable because they did not consider the whether the differences in properties, if any, were attributable to the stretching and/or heating.

6. My opinion is supported by the depositions of Mr. Hallett and Mr. Lewis in June 2006 and Pearsalls' manufacturing documents which show that the samples tested by Dr. Gitis were manufactured differently. I understand from counsel that Dr. Gitis tested FiberWire samples from Pearsalls batch 28893. Based on the deposition transcripts of Mr. Hallett and Mr. Lewis, I understand that the untreated FiberWire from batch 28893 that was used in Dr. Gitis' tests did not undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 17:18-21; 18:15-17; 24:2-8). In this report, I refer to

the “uncoated” samples tested by Dr. Gitis as the untreated samples because this is a more accurate description. I also understand that the treated FiberWire sample that Dr. Gitis used did undergo the heating, stretching, and coating processes shown in Pearsalls’ manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 27:10-25; Ex. LL at PR08466). I refer to the “coated” samples tested by Dr. Gitis as the treated samples.

7. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ processes used to manufacture FiberWire. During the inspection of the Pearsalls’ manufacturing facility, I personally witnessed the coating, heating, and stretching process used to make FiberWire. While at the inspection, I saw the stretching process. I saw exemplar pads that are tightened against the suture. The tightening of the pads against the suture provides a frictional force that must be overcome. This results in the suture being stretched as it is pulled at a rate of about 20 meters per minute. During my inspection, I plucked the FiberWire moving through the treating operations. Based on its resistance to transverse deformation, I observed that the FiberWire was under tension. I understand that Pearsalls refers to this manufacturing step as stretching (Ex. JJ; Ex. MM, Hallett Dep. at 32:12-14).

8. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ heat-treating process used to manufacture FiberWire. During my visit to Pearsalls’ facility, I also saw the equipment that is used for the heat-treating operations. I learned that the FiberWire sutures are processed by traversing the suture through a hot-air, four-stage convection oven while under tension. The suture threadline speed through the oven is generally 20 meters/minute and each stage of the four-stage oven was about 2 meters in length (Ex. MM, Hallett Dep. at 110:18-21). Accordingly, the suture



threadline has a residence time in each zone equal to about 6 seconds. Zones 1 and 2 are heated with hot air at 100°C (Ex. LL at PR8466). Zone 3 is heated with hot air at 130°C, and zone 4 is heated with hot air at 170°C (Ex. LL at PR8466). Thus, as the suture passes through the oven, the UHMWPE and PET braid is heated above 100°C but less than 170°C. The photographs that are attached to my expert report dated March 3, 2006 clearly show that the fibers have not fused or melted together.

9. It is my opinion that Pearsalls' heating and stretching processes affects FiberWire's properties. For example, it is my opinion that Pearsalls' heating and stretching processes will eliminate or reduce any minor bumps or irregularities along the suture surface, resulting in a smoother surface. This is described in the 446 Patent (Ex. D to my First Report at 5:61-6:1). Because heating and stretching affects surface properties, it affects the following suture properties: knot slippage, knot run-down, friction, chatter, and tissue drag. Since Dr. Gitis tested for these properties and Pearsalls' heating and stretching processes affect them, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire. My opinion is supported by the testimony of Dr. Mukherjee who testified that hot stretching processes affect a suture's strength and handling properties (Ex. NN, Mukherjee Dep. at 106:18-109:5; 110:2-4). Also, Pearsalls' heating and stretching processes affect pliability because they affect the moment of inertia, the modulus of the fibers, and the fiber-to-fiber interaction. Since Dr. Gitis tested for pliability and Pearsalls' heating and stretching affects pliability, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire.

10. Dr. Gitis tested untreated and treated FiberWire. As I understand his tests, he did not account for the stretching and heat-treating differences between the treated and untreated samples. Nor did Dr. Mukherjee account for these differences. Thus, they did not account for

whether the differences between the samples were due to differences between the heated and stretched UHMWPE/PET braid. Since the stretching and heat treating affects the properties for which Dr. Gitis was testing, it is not scientifically acceptable to attribute the differences in Dr. Gitis' results to only the coating on FiberWire.

#### **IV. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because the Testing Methodology Is Either Flawed or Unexplained**

##### **A. Dr. Gitis' "Pliability" Test and Methodology Was Flawed**

11. Dr. Gitis' "pliability" test is scientifically unacceptable because it is based on:

(1) stiffness data determined by a test using non-uniform loading rates; (2) flawed diameter measurements; (3) flawed assumptions about the moment of inertia, as discussed in my previous report (and not repeated here); and (4) unexplained methodology for calculating "stiffness."

##### **1. Dr. Gitis' Pliability Tests Are Scientifically Unacceptable Because They Used Non-Uniform Loading Rates**

12. Dr. Gitis used a tensile test to measure a parameter that he used to determine pliability. As I described in my Rebuttal Expert Report, I do not believe that this is an accurate methodology for testing FiberWire's pliability. But even if it were to be used, the testing methodology would have to be reliable. Here, it was not.

13. There are two accepted ways to perform a tensile test. One is a constant rate of extension test. For this test, a tensile specimen is secured between two jaws; one is stationary, and the other extends at a constant rate with regard to time. A load cell is also connected linearly to one of the jaws. The load cell measures the tensile force in the specimen, as it is being extended. Thus, the test yields data for plotting force vs. extension, and from this data the specimen's force vs. elongation behavior can be determined. It is my experience that this tensile testing method is the most commonly used and accepted tensile test by those who regularly perform tensile tests

on linear structures such as sutures. This test is described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

14. The other accepted way to perform a tensile test is known as a constant rate of loading test. For this test, a tensile specimen is secured between two jaws with one being stationary and the other permitted to move such that the measured loads, which are also measured by a load cell, are increasing at a constant rate. This test is also described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

15. For the constant rate of loading test, the loading rate must be the same because it is well known that fibers, such as those used in FiberWire, are materials having time-dependent, visco-elastic behavior. For these types of materials, it is scientifically unreliable to draw any conclusions by comparing the stress-strain relationship of specimens with different loading rates.

16. Dr. Gitis states in his report that the “pliability” tests were conducted by the constant rate of loading method. In that regard, he states in his report that the force was “uniformly increasing at the rate of 0.33 kg./sec.” I have examined the underlying data produced by Dr. Gitis and CETR. Based on my analysis of this data, the tests were not conducted as stated in Dr. Gitis’ report. Dr. Gitis used different loading rates on each sample. I used the TRENDLINE function incorporated in MS Excel software, on the modulus data in the Excel file provided to me, to determine the loading rate for each sample and the regression factor ( $R^2$ , a measurement of the confidence between the actual data and curve or line which defines that data) and obtained the

following results:

	Untreated Sample Loading Rate, kg/sec	R <sup>2</sup>	Treated Sample Loading Rate, kg/sec	R <sup>2</sup>
1	0.094	0.9981	0.144	0.9984
2	0.060	0.9787	0.103	0.9931
3	0.074	0.9886	0.090	0.9947
4	0.050	0.9979	0.121	0.9988
5	0.036	0.9979	0.109	0.9968
6	0.073	0.9970	0.110	0.9890
7	0.053	0.9973	0.133	0.9905
8	0.058	0.9985	0.080	0.9925
Avg.	0.062		0.108	

As can be seen from this table, the load rates varied significantly between individual samples and even among the treated and untreated samples. In fact, the average loading rate for the untreated samples is approximately 75% greater than the average loading rate for the treated samples. Further, since the TRENDLINE function uses a linear relationship and the R<sup>2</sup> values are greater than the 95% accepted confidence level, the determined loading rates are accurate.

17. Consequently, no scientifically reliable “stiffness” conclusions can be drawn based on Dr. Gitis’ tests because the loading rate for each of the individual samples was not the same. Neither Dr. Gitis nor Dr. Mukherjee accounted for the differences in loading rate. Therefore, any conclusions that they drew from this data and the “stiffness” values reported by Dr. Gitis are neither reliable nor comparable. In fact, Dr. Gitis testified that if the sample load rates were different, it would “jeopardize the results” (Ex. PP, Gitis Dep. at 163:17).

## 2. Dr. Gitis’ Pliability Tests Are Scientifically Unreliable Because He Used the Wrong Diameter

18. In determining “stiffness,” Dr. Gitis assumed a monofilament circular structure. He also determined stiffness based on the moment of inertia, which is a function of the diameter raised to

the fourth power for a circular monofilament.<sup>1</sup> As I discussed in my previous report, I disagree with this assumption, but assuming that it is correct, it is important to use the correct diameters. This is because any error in the diameter between the treated and untreated samples results in an error in the “stiffness” values calculated by Dr. Gitis. It is my opinion that Dr. Gitis did not use accurate diameter measurements, and therefore, Dr. Gitis’ reported stiffness values are not scientifically acceptable.

19. I understand that Dr. Gitis used the same diameter for the treated and untreated FiberWire samples. That diameter was 0.65 mm (Gitis Report at 3). I understand from Dr. Gitis’ deposition that CETR measured the samples’ diameters with a caliper (Ex. PP, Gitis Dep. at 153:11-20). I am not able to fully review and analyze Dr. Gitis’ diameter measurements because he did record these measurements or the testing methodology (Ex. PP, Gitis Dep. at 174:7-10).

20. It is my opinion that Dr. Gitis’ measurements are inaccurate. Dr. Gitis’ diameter measurements contradict the measurements taken by Pearsalls. I have reviewed PR08456-57 (Ex. QQ). These documents show that Pearsalls measured the treated FiberWire’s average diameter as 0.586 mm and the untreated FiberWire’s average diameter as 0.600 mm. Therefore, Dr. Gitis’ measurements are different than Pearsalls’ measurements. In fact, Pearsalls measured the maximum diameter of the treated suture as 0.599 mm and the maximum diameter of the untreated suture as 0.635 mm., which are both less than the 0.65 mm diameter used by Dr. Gitis.

21. It is my opinion that Pearsalls uses a more accurate methodology for measuring diameter than Dr. Gitis. I understand that Pearsalls measures the diameter according to its TM36 procedure (Ex. JJ; Ex. RR; Ex. SS; Ex. TT, Hallett Dep. at 40:8-42:4; Ex. MM, Hallett Dep. at

---

<sup>1</sup> Dr. Gitis’ reported stiffness values also are dependent upon his assumption that the treated and untreated samples had a uniform circular cross-section. This not a correct assumption either.



174:12-20; 179:19-180:23; 185:4-9). Pearsalls' diameter measurement procedure (TM36) is stated to be performed according to the European pharmacopoeia (Ex. SS at PR8444). According to Pearsalls, the testing is accurate to 0.002 mm. (Ex. SS).

22. It is my opinion that Pearsalls' diameter measurement methodology is more accurate and scientifically reliable than using a caliper because it measures and keeps the transverse force constant. Dr. Gitis did not provide any information on whether he kept the transverse "crushing" force constant when he measured the sutures. Keeping the transverse "crushing" force constant is important because sutures are relatively compliant in transverse compression, indicating that they can deform during measurement and thereby yield inaccurate measurements. Because Dr. Gitis used a value (*i.e.*, 0.65 mm) that is higher than any valued measured by Pearsalls for the treated and untreated samples, obtained the same value for the treated and untreated samples, did not account for the "crushing" force, and used a caliper, it is my opinion that he did not use a scientifically reliable method for determining diameter.

### **3. The Stiffness Values Calculated By Dr. Gitis Were Not Performed With Scientifically Reliable Methods**

23. Dr. Gitis purports to determine the stiffness values in Table 1 of his report by using the relationship between modulus of elasticity and moment of inertia. As I understand his methodology, Dr. Gitis determined the stiffness values according to the formula  $(\text{slope}/(3.14 * D^2/4)) * D^4/64$ . This is mathematically equivalent to  $(\text{slope} * D^2)/16$ . He used a diameter of 0.65 mm, and the slope was purportedly determined from the data he obtained from his tests.

24. His calculations are based on the determination of the slope of the force v. strain curves. I tried to reproduce his calculations but was not able to obtain the same results that he lists in Table 1. Dr. Gitis did not state in his report how he calculated the slope.

At deposition, Dr. Gitis testified that he calculated the slope of the curves by taking the change in force after the preload was set to the completion of the test, and divided that by the strain between after the preload was applied and the end of the test (Ex. PP, Gitis Dep. at 187:8-15). Although this is not a scientifically acceptable methodology, it will work if the data is a straight line or the best fit through the data is essentially linear. My review of the data indicates that it essentially follows a straight line relationship. Thus, I determined the slope and the stiffness values as Dr. Gitis states that he did, but I did not generate the same stiffness values (Ex. UU). This means that Dr. Gitis did not determine slope as he stated in his deposition. I do not know what methodology he used to determine slope.

25. I also tried to determine Dr. Gitis' stiffness values by fitting a best straight line through the data following the pre-load and determining the slope of that curve. This is a scientifically acceptable method for determining slope. I used the TRENDLINE function, which produces a linear regression analysis, incorporated in MS Excel software to determine the slope of each data set and the  $R^2$  factor derived from each of the 16 sutures. I then multiplied each of the slope values by the diameter squared and divided it by 16, as Dr. Gitis suggested (Ex. PP, Gitis Dep. at 186:7-11).

The following table represents the pliability or stiffness for each of the 16 tested sutures using this method for determining slope.

	Treated, kg* m <sup>2</sup>	R <sup>2</sup>	Untreated, kg* m <sup>2</sup>	R <sup>2</sup>
1	8.71E-07	0.9974	7.50E-07	0.9936
2	3.74E-07	0.9883	7.23E-07	0.9983
3	6.17E-07	0.9936	9.17E-07	0.9980
4	3.58E-07	0.9915	7.49E-07	0.9955
5	2.81E-07	0.9904	5.35E-07	0.9831
6	4.28E-07	0.9891	1.00E-06	0.9766
7	3.99E-07	0.9984	1.04E-06	0.9958
8	3.40E-07	0.9906	8.24E-07	0.9976
Avg.	4.59E-07		8.18E-07	

As can be seen from this table, these pliability values are different than the ones reported in Dr. Gitis' report. Therefore, I do not understand what methodology Dr. Gitis used for determining slope and the "stiffness" values in Table 1 of his report. Because he has not shown what methodology he used, his methodology cannot be said to be scientifically acceptable.

26. I also note that Dr. Gitis' "pliability" test data details a parameter called "ZABS." I do not know what this parameter means, and Dr. Gitis was unable to explain what it means (Ex. PP, Gitis Dep. at 143:7-13). Thus, depending on what the parameter means, it may further affect my opinions.

**B. No Reliable Conclusions About Pliability Can Be Drawn From Dr. Gitis' "Pliability" Test Because The Results Are Contradicted By Dr. Gitis' Tissue Drag Test**

27. If the pliability test performed by Dr. Gitis is assumed to be reliable (it is my opinion that it is not) and the tissue drag test performed by Dr. Gitis is also assumed to be reliable (it is my opinion that it is not as described below), the "pliability" results from each test should be consistent. It is my opinion that the "pliability" results from each of these tests is not consistent and therefore no reliable conclusions about pliability can be drawn from Dr. Gitis' tests, even if

they were assumed to be proper tests. My analysis below assumes that the tissue drag test is a proper and reliable test. But it is not because the samples have differences other than coating, it incorrectly assumes a monofilament structure, it incorrectly assumes a circular cross section, it incorrectly assumes a constant diameter for all samples, and it assumes that the tissue-drag tests were done properly, which they were not.

28. The tissue drag test is described on page 12 of the CETR report. In the report, it is stated that a 20 mm length of suture was extended at a constant rate of 1 mm/sec while continuously recording the pulling force. Prior to the suture slipping, the test is similar to that specified in ASTM D2256-02 "Standard test method for tensile properties of yarn by the single strand method." Thus, putting aside the incorrect assumptions inherent in Dr. Gitis' tests and the flaws in the tissue drag tests (see below), prior to slipping between the leather pads, the recorded data can be used to determine the force/elongation relationship of the tested specimens.

29. I examined the data before slippage between the leather pads from the time period 0.1 to 0.5 seconds. This was to ensure that the time period of collected data was the same for each suture.

30. After examining the data, I plotted the individual force vs. strain data relationship for each of the eight coated and eight uncoated sutures. These plots are attached to this report as Ex. VV. I then used the TRENDLINE function incorporated in MS Excel software to determine the slope of each curve derived from each of the 16 sutures. These slopes represent the force on the thread line at a given time, or stated another way, force per unit time. Dr. Gitis reported that the specimens were originally 20 mm and the jaw moved at a constant rate of 1 mm/sec.

Accordingly, the strain rate on the specimen was 0.05 (mm/mm)/sec. I then divided the slope of each curve by 0.05/sec (the strain rate) and the assumed cross sectional area of each suture

(based on Dr. Gitis' assumed 0.65 mm) to obtain the tensile modulus. I then multiplied this value by the moment of inertia, based on Dr. Gitis' incorrect assumptions, to obtain the "pliability or stiffness" data for each suture. The following table represents the pliability or stiffness data for each of the 16 samples from the tissue drag test.

Specimen	Untreated, kg* m <sup>2</sup>	R <sup>2</sup>	Treated, kg* m <sup>2</sup>	R <sup>2</sup>
1	4.10E-07	0.9966	7.07E-07	0.9990
2	4.07E-07	0.9967	4.98E-07	0.9935
3	3.87E-07	0.9949	3.74E-07	0.9939
4	3.45E-07	0.9945	7.82E-07	0.9949
5	3.46E-07	0.9944	7.03E-07	0.9549
6	3.08E-07	0.9918	3.07E-07	0.9852
7	4.37E-07	0.9947	4.39E-07	0.9949
8	3.71E-07	0.9945	4.85E-07	0.9921
Avg.	3.76E-07		5.37E-07	

31. Based on this analysis, the tissue drag tests shows that the stiffness of the untreated suture was less than the stiffness of the treated suture. This contradicts what Dr. Gitis reported for his "pliability" test in Table 1 of his report where he reports that that the stiffness of the untreated suture was higher than the treated suture. Thus, even assuming his tests were done properly, no reliable conclusions can be drawn from them because the data from the tissue drag test contradicts the data from the "pliability" test.

**V. Dr. Gitis' Knot Slippage Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

32. It is my opinion that Dr. Gitis did not determine the knot slippage strength using a scientifically reliable testing methodology. According to Dr. Gitis report, his methodology is described on page 5 of his report. He states that the parallel rods were pulled apart at a constant velocity of 1 mm/sec. While the rods were pulled, CETR personnel measured and recorded the force until either the knot untied or 3 mm of slippage occurred. However, the tests were not conducted as stated in his report.



33. I examined the underlying data of the knot slippage test and Dr. Gitis' deposition testimony. According to Dr. Gitis, the Z column in the knot slippage data is the vertical displacement of rods (Ex. PP, Gitis Dep. at 230:12-14). Consequently, if the test was performed at a constant velocity as stated in the test report, the Z value should increase 1 mm every second. However, the data does not show this. In fact, the data shows that the displacement decreases with increasing time. At deposition, Dr. Gitis testified that the data was not consistent with a constant velocity of 1 mm/sec. (Ex. PP, Gitis Dep. at 246:9-12). Further, Dr. Gitis was not able to explain why the data showed that the Z value decreased (Ex. PP, Gitis Dep. at 245:13-19). Also, he could not fully explain what the data in the  $F_x$  and  $F_y$  columns represented (Ex. PP, Gitis Dep. at 229:16-20). Therefore, the test was not performed as reported, and the data is not explained. Based on the information provided, the testing methodology is not a scientifically acceptable test because there is no adequate explanation of the test methods or the data. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot slippage strength values are just data without meaning and context, and they cannot be scientifically relied upon.

#### **VI. Dr. Gitis' Knot Run-Down Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

34. It is my opinion that Dr. Gitis did not determine the knot run-down using a scientifically reliable test methodology. His methodology is partially described on page 7 of his report. However at deposition, Dr. Gitis could not fully describe the test methodology for this test. He testified that he did not know: (i) how the suture was attached to the upper brass rod (Ex. PP, Gitis Dep. at 236:3-9); and (ii) what he did with the lower end of the suture (Ex. PP, Gitis Dep. at 236:23-237:1). Dr. Gitis stated that he didn't remember how the test was conducted (Ex. PP, Gitis Dep. at 237:8-12). Thus, based on the information provided, the test, as described, is not a scientifically acceptable test because there is no adequate explanation of the test methods or how

the data was obtained. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot run-down values are just data without meaning and context, and they cannot be scientifically relied upon.

35. Although Dr. Gitis' knot-run down data is unreliable, even if were to be relied upon, it is inconclusive. Dr. Gitis' test results show in Table 3 that two of the treated samples had the same knot-run down force as two of the untreated samples. If coating has a material effect on knot run-down, then I do not understand why on two occasions the untreated samples had the same knot run-down force as two of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this (Ex. PP, Gitis Dep. at 218-226; Ex. WW, Mukherjee Dep. at 451:3-12). Absent an explanation, it is my further opinion that it is not scientifically reliable to conclude from the data that coating causes a smaller knot run-down force.

36. Also, I do not fully understand Dr. Gitis' knot run-down data because he could not explain it. He did not know what the data in the  $F_f$  column represented (Ex. PP, Gitis Dep. 241:10-11), and how the tests were conducted. Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

37. Further, I do not understand Dr. Gitis' methodology for reporting his data because the data he generated does not appear to correspond to the reported values in Table 3. For example, Dr. Gitis' data shows that coated sample 7 appeared to have the highest knot run-down peak force (Ex. XX, coated sample 7 denoted by blue unfilled circles). Yet, his reported data in Table 3 differs because coated sample 7 had a value of 0.19 kg., which was not the highest value reported in the chart. Dr. Gitis was not able to explain this difference (Ex. PP, Gitis Dep. at 242:16-243:4). Thus, I do not understand what methodology Dr. Gitis used, and his unknown methodology cannot be considered reliable.

**VII. Dr. Gitis' Friction Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

38. Dr. Gitis' friction tests are scientifically unreliable because the testing methodology was flawed, and there was no explanation of how the coefficient of friction was determined. Dr. Gitis' report partially describes the friction tests on page 9. According to Dr. Gitis, two sutures were each held in a suture holder by clamping one suture end and holding the other suture end by tightening a screw against the suture (Ex. PP, Gitis Dep. at 249:4-21). Dr. Gitis did not measure the clamping force (Ex. PP, Gitis Dep. at 249:22-24). Further, he did not measure the torque on the screw or the force placed on the suture by the screw (Ex. PP, Gitis Dep. at 249:25-250:2). Nor did he accurately control how tight the screw was placed against the suture (Ex. PP, Gitis Dep. at 250:16-252:9). Because Dr. Gitis' friction tests relies on rubbing two sutures against each other, the tension under which the sutures are subject to in the holder affects the measured friction parameters. Because Dr. Gitis did not use a scientifically reliable method to check the tension on the sutures in the suture holders, no scientific reliable conclusions can be drawn based on his friction tests.

39. Based on the information that was provided, Dr. Gitis' friction test methodology is also not scientifically reliable because he could not explain how his testing machine and software determined the coefficient of friction (Ex. PP, Gitis Dep. at 261:10-14; 263:14-265:6). Absent an explanation of how the friction coefficients were determined, they are values without any meaning, and they cannot be scientifically relied upon to determine the coefficient of friction.

40. Also, I do not fully understand Dr. Gitis' friction data because he could not explain it. He did not know what the  $F_f$  represented (Ex. PP, Gitis Dep. at 261:1-9). Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

**VIII. Dr. Gitis' Chatter Data Is Unreliable Because the Testing Methodology Is Not Known**

41. It is my opinion that Dr. Gitis' chatter data on page 11 of his report is not scientifically reliable because no explanation was provided as to how it was determined. Dr. Gitis provides a brief explanation on page 11 of his report but does not explain specifically how it was determined (*i.e.* he does not explain what "maximum and minimum" amplitudes were used and how they were used to generate the results from the friction and knot run-down tests). At his deposition, he was not able to explain how the chatter values were determined (Ex. PP, Gitis Dep. at 268:1-269:5). Therefore, absent an explanation of how the chatter values were determined, they are just values without any meaning, and they cannot be scientifically relied upon to draw conclusions.

42. Also, it appears that certain data related to Dr. Gitis' chatter determinations were not maintained by Dr. Gitis (Ex. PP, Gitis Dep. at 267:10-23). Since I did not have the opportunity to review the data, I cannot use it to understand whether Dr. Gitis used a scientifically acceptable method.

43. Further, Dr. Gitis' tests also show that one of the treated samples had about the same chatter value (0.012) as at least four of the untreated samples (0.013, 0.013, 0.012, 0.011), and another of the treated samples (0.010) had a value that was the same as at least one of the untreated samples (0.011). If coating had a material effect on chatter, then I do not understand why some of the untreated samples had the same chatter value as some of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this discrepancy (Ex. PP, Gitis Dep. at 269:22-270:2; Ex. WW, Mukherjee Dep. at 464:21-465:4). Based on these results, it is my further opinion that it is not scientifically reliable to conclude from the data that coating materially affects FiberWire's chatter.

**IX. Dr. Gitis' Tissue Drag Data Is Unreliable Because the Testing Methodology Is Flawed**

44. Dr. Gitis' tissue drag test involved dragging a suture through two pieces of leather that were clamped together. The results of the tissue drag test are a function of how tight the leather was clamped against the suture. If the force applied to the suture by the leather differed between samples, this will lead to different results that cannot be compared. Dr. Gitis clamped the leather together with a nut and bolt (Ex. PP, Gitis Dep. at 272:24-273:1). But Dr. Gitis did not control the force that was applied to the leather or how tightly the sutures were clamped between the leather (Ex. PP, Gitis Dep. at 273:2-5). Thus, because Dr. Gitis did not control the clamping force, he did not use a scientifically reliable methodology for performing the tissue-drag test, and it is not scientifically acceptable to compare the data he obtained between samples.

45. I also note that Dr. Gitis states in his report at page 12 that he conducted a second different tissue drag test with a needle. He did not provide any data or results from this test in his report or subsequent to his report. I understand that he no longer has the data (Ex. PP, Gitis Dep. at 271:10-272:9). Thus, I have not been provided the opportunity to assess this test or its results. It could be that this test contradicts his other tests, but I do not know because I have not seen the data.

46. Also, I note that Dr. Gitis' tissue drag data does not seem to correlate with his reported data. For example, his data shows that untreated sample 5 (magenta) had the highest static tissue-drag force (Ex. YY). But his report in table 6 shows that the highest static tissue-drag force for the untreated samples was sample no. 4. Dr. Gitis was not able to explain this discrepancy (Ex. PP, Gitis Dep. at 279:11-280:5). Thus, it is not clear what methodology Dr. Gitis used to obtain his reported tissue drag values. Therefore, for this additional reason, his unknown methodology cannot be considered scientifically reliable.



**X. Arthrex's Knot-Down Test Is Scientifically Unreliable For Assessing The Effects of FiberWire's Coating on FiberWire's Properties**

47. Dr. Mukherjee also relies on a "knot-tie down" test performed by Arthrex (Ex. 19 to Dr. Mukherjee's Responsive Report, see Mukherjee's Responsive Report at 24-25), which purportedly shows the effects of FiberWire's coating on knot tie-down properties. I am not aware of any documentation that establishes the construction and manufacturing processes that were used to construct the "uncoated" suture used in this test. Therefore, absent information about the construction and manufacturing of the tested samples, it is not possible to say that the only difference between the samples was coating. Further, it is scientifically unreliable to attribute the differences in the test results to coating.

48. I understand that Arthrex's counsel has indicated that the samples produced as ARM 25452 (DM Ex. 430) may be uncoated sutures from the same batch as that used in Arthrex's knot tie-down test. The sample designated as ARM25452 is white and does not have FiberWire's blue dye. I note that Mr. Grafton's email from July 2004 indicates that the "uncoated" samples used in Arthrex's knot-run down test were "removed from production before dying and coating" (Ex. ZZ). The sample and Mr. Grafton's email suggest that the untreated samples used in Arthrex's knot tie down test was not dyed, scoured, coated, stretched, or heated. Therefore, even if the sample known as ARM 25452 is the type that was tested by Arthrex, there is no scientific reliable method for making any conclusions about the materiality of the affects of FiberWire's coating on FiberWire's properties.

**XI. The FiberWire Photos Provided in Dr. Gitis' Report Do Not Show Coating**

49. Based on the information provided about the pictures shown in Dr. Gitis' report it, I cannot determine whether they show any coating. My opinion is supported by Dr. Gitis who stated that he could not see coating when he observed the samples under magnification (Ex. PP,

Gitis Dep. at 285:9-14). I understand that Dr. Mukherjee has opined that Figure 14 in Dr. Gitis' report shows coated sutures because the fibers are allegedly spaced closer together (Ex. WW, Mukherjee Dep. at 461:23-462:10). It is my opinion that this is not a scientifically acceptable analysis or conclusion. I understand from Dr. Gitis' and Dr. Mukherjee's testimony that it is not known what part of FiberWire is shown in the photos, and it is not known how exactly the material shown was handled (Ex. WW, Mukherjee Dep. at 462:12-18; Ex. PP, Gitis Dep. at 289:8-16). Thus, the spacing between the fibers could be a function of how the sutures were handled, cut, or clamped during the photos, as described by Dr. Gitis (Ex. PP, Gitis Dep. at 288:12-20). There is no reliable methodology provided by Dr. Mukherjee for opining that Figure 14 shows coating. I note that Dr. Gitis had other pictures taken but did not provide them for analysis (Ex. PP, Gitis Dep. at 286:7-17).

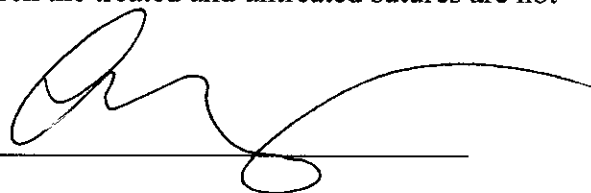
## **XII. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material**

50. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. AAA, Burks' Dep. at 87:7-13; 88:1-3; 96:18-19; 98:19-25). He also stated that he could not "clearly feel a difference" (Ex. AAA, Burks Dep. at 88:9-10). This supports my opinion that any purported differences are not material.

51. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (Ex. AAA, Burks Dep. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (Ex. AAA, Burks Dep. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (Ex. AAA, Burks. Dep. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in

surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 14, 2006

A handwritten signature in black ink, consisting of a large, stylized 'D' followed by a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.  
Fellow-American Society of Mechanical Engineers


**CERTIFICATE OF SERVICE**

I certify that the foregoing Supplemental Expert Report of Dr. David Brookstein was served in the manner indicated below on July 14, 2006 on the following:

*Via e-mail without exhibits and  
via Federal Express Saturday delivery (with exhibits)*  
Charles W. Saber  
Dickstein Shapiro LLP  
1825 Eye Street NW  
Washington D.C. 20006-5403  
saberc@dsmo.com

*Via Federal Express*  
Christopher Weld, Jr.  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109

Dated: July 14, 2006

  
\_\_\_\_\_  
Erich M. Falke

# **EXHIBIT 14**



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.,</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom,</b>	)	
	)	
<b>Defendants.</b>	)	

**Amended Supplemental Expert Report of Dr. David Brookstein**

**I. Background Information**

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

**II. Summary of Opinions**

2. The samples tested by Dr. Gitis that he labeled “coated” and “uncoated” were manufactured differently. These manufacturing differences affect FiberWire’s UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire’s coating based on Dr. Gitis’ tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

3. It is my opinion that Dr. Gitis' testing methodology was not based on accepted scientific methods or he failed to provide information that showed that his tests and analysis were based on accepted scientific methods. Therefore, it is my opinion that his tests and data cannot be relied on to analyze the effects, if any, of FiberWire's coating on the suture's properties.

4. It is my opinion that no reliable conclusions can be made about the effect, if any, of FiberWire's coating on the suture's properties based on Arthrex's knot tie-down test because either the "coated" or "uncoated" samples were manufactured differently or it is not known how they were manufactured.

### **III. Dr. Gitis' Tests Are Scientifically Unreliable Because The Tested Samples Differed In How They Were Manufactured**

5. Dr. Gitis tested samples in which the only purported difference between the samples was that one set was "coated" and the other set was not. But the samples differed in more respects than just coating. Specifically, the "uncoated" sample was not heated and stretched, but the "coated" sample was heated and stretched twice, as is the case during the typical manufacturing of FiberWire sutures. Therefore, any conclusions that Dr. Mukherjee and Dr. Gitis made about the effect of a coating based on Dr. Gitis' tests are not reliable because they did not consider the whether the differences in properties, if any, were attributable to the stretching and/or heating.

6. My opinion is supported by the depositions of Mr. Hallett and Mr. Lewis in June 2006 and Pearsalls' manufacturing documents which show that the samples tested by Dr. Gitis were manufactured differently. I understand from counsel that Dr. Gitis tested FiberWire samples from Pearsalls batch 28893. Based on the deposition transcripts of Mr. Hallett and Mr. Lewis, I understand that the untreated FiberWire from batch 28893 that was used in Dr. Gitis' tests did not undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 17:18-21; 18:15-17; 24:2-8). In this report, I refer to

the “uncoated” samples tested by Dr. Gitis as the untreated samples because this is a more accurate description. I also understand that the treated FiberWire sample that Dr. Gitis used did undergo the heating, stretching, and coating processes shown in Pearsalls’ manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 27:10-25; Ex. LL at PR08466). I refer to the “coated” samples tested by Dr. Gitis as the treated samples.

7. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ processes used to manufacture FiberWire. During the inspection of the Pearsalls’ manufacturing facility, I personally witnessed the coating, heating, and stretching process used to make FiberWire. While at the inspection, I saw the stretching process. I saw exemplar pads that are tightened against the suture. The tightening of the pads against the suture provides a frictional force that must be overcome. This results in the suture being stretched as it is pulled at a rate of about 20 meters per minute. During my inspection, I plucked the FiberWire moving through the treating operations. Based on its resistance to transverse deformation, I observed that the FiberWire was under tension. I understand that Pearsalls refers to this manufacturing step as stretching (Ex. JJ; Ex. MM, Hallett Dep. at 32:12-14).

8. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ heat-treating process used to manufacture FiberWire. During my visit to Pearsalls’ facility, I also saw the equipment that is used for the heat-treating operations. I learned that the FiberWire sutures are processed by traversing the suture through a hot-air, four-stage convection oven while under tension. The suture threadline speed through the oven is generally 20 meters/minute and each stage of the four-stage oven was about 2 meters in length (Ex. MM, Hallett Dep. at 110:18-21). Accordingly, the suture

threadline has a residence time in each zone equal to about 6 seconds. Zones 1 and 2 are heated with hot air at 100°C (Ex. LL at PR8466). Zone 3 is heated with hot air at 130°C, and zone 4 is heated with hot air at 170°C (Ex. LL at PR8466). Thus, as the suture passes through the oven, the UHMWPE and PET braid is heated above 100°C but less than 170°C. The photographs that are attached to my expert report dated March 3, 2006 clearly show that the fibers have not fused or melted together.

9. It is my opinion that Pearsalls' heating and stretching processes affects FiberWire's properties. For example, it is my opinion that Pearsalls' heating and stretching processes will eliminate or reduce any minor bumps or irregularities along the suture surface, resulting in a smoother surface. This is described in the 446 Patent (Ex. D to my First Report at 5:61-6:1). Because heating and stretching affects surface properties, it affects the following suture properties: knot slippage, knot run-down, friction, chatter, and tissue drag. Since Dr. Gitis tested for these properties and Pearsalls' heating and stretching processes affect them, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire. My opinion is supported by the testimony of Dr. Mukherjee who testified that hot stretching processes affect a suture's strength and handling properties (Ex. NN, Mukherjee Dep. at 106:18-109:5; 110:2-4). Also, Pearsalls' heating and stretching processes affect pliability because they affect the moment of inertia, the modulus of the fibers, and the fiber-to-fiber interaction. Since Dr. Gitis tested for pliability and Pearsalls' heating and stretching affects pliability, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire.

10. Dr. Gitis tested untreated and treated FiberWire. As I understand his tests, he did not account for the stretching and heat-treating differences between the treated and untreated samples. Nor did Dr. Mukherjee account for these differences. Thus, they did not account for

whether the differences between the samples were due to differences between the heated and stretched UHMWPE/PET braid. Since the stretching and heat treating affects the properties for which Dr. Gitis was testing, it is not scientifically acceptable to attribute the differences in Dr. Gitis' results to only the coating on FiberWire.

#### **IV. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because the Testing Methodology Is Either Flawed or Unexplained**

##### **A. Dr. Gitis' "Pliability" Test and Methodology Was Flawed**

11. Dr. Gitis' "pliability" test is scientifically unacceptable because it is based on:

(1) stiffness data determined by a test using non-uniform loading rates; (2) flawed diameter measurements; (3) flawed assumptions about the moment of inertia, as discussed in my previous report (and not repeated here); and (4) unexplained methodology for calculating "stiffness."

##### **1. Dr. Gitis' Pliability Tests Are Scientifically Unacceptable Because They Used Non-Uniform Loading Rates**

12. Dr. Gitis used a tensile test to measure a parameter that he used to determine pliability. As I described in my Rebuttal Expert Report, I do not believe that this is an accurate methodology for testing FiberWire's pliability. But even if it were to be used, the testing methodology would have to be reliable. Here, it was not.

13. There are two accepted ways to perform a tensile test. One is a constant rate of extension test. For this test, a tensile specimen is secured between two jaws; one is stationary, and the other extends at a constant rate with regard to time. A load cell is also connected linearly to one of the jaws. The load cell measures the tensile force in the specimen, as it is being extended. Thus, the test yields data for plotting force vs. extension, and from this data the specimen's force vs. elongation behavior can be determined. It is my experience that this tensile testing method is the most commonly used and accepted tensile test by those who regularly perform tensile tests



on linear structures such as sutures. This test is described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

14. The other accepted way to perform a tensile test is known as a constant rate of loading test. For this test, a tensile specimen is secured between two jaws with one being stationary and the other permitted to move such that the measured loads, which are also measured by a load cell, are increasing at a constant rate. This test is also described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

15. For the constant rate of loading test, the loading rate must be the same because it is well known that fibers, such as those used in FiberWire, are materials having time-dependent, visco-elastic behavior. For these types of materials, it is scientifically unreliable to draw any conclusions by comparing the stress-strain relationship of specimens with different loading rates.

16. Dr. Gitis states in his report that the “pliability” tests were conducted by the constant rate of loading method. In that regard, he states in his report that the force was “uniformly increasing at the rate of 0.33 kg./sec.” I have examined the underlying data produced by Dr. Gitis and CETR. Based on my analysis of this data, the tests were not conducted as stated in Dr. Gitis’ report. Dr. Gitis used different loading rates on each sample. I used the TRENDLINE function incorporated in MS Excel software, on the modulus data in the Excel file provided to me, to determine the loading rate for each sample and the regression factor ( $R^2$ , a measurement of the confidence between the actual data and curve or line which defines that data) and obtained the

following results:

	Treated Sample Loading Rate, kg/sec	R <sup>2</sup>	Untreated Sample Loading Rate, kg/sec	R <sup>2</sup>
1	0.094	0.9981	0.144	0.9984
2	0.060	0.9787	0.103	0.9931
3	0.074	0.9886	0.090	0.9947
4	0.050	0.9979	0.121	0.9988
5	0.036	0.9979	0.109	0.9968
6	0.073	0.9970	0.110	0.9890
7	0.053	0.9973	0.133	0.9905
8	0.058	0.9985	0.080	0.9925
Avg.	0.062		0.108	

As can be seen from this table, the load rates varied significantly between individual samples and even among the treated and untreated samples. In fact, the average loading rate for the untreated samples is approximately 75% greater than the average loading rate for the treated samples. Further, since the TRENDLINE function uses a linear relationship and the R<sup>2</sup> values are greater than the 95% accepted confidence level, the determined loading rates are accurate.

17. Consequently, no scientifically reliable “stiffness” conclusions can be drawn based on Dr. Gitis’ tests because the loading rate for each of the individual samples was not the same. Neither Dr. Gitis nor Dr. Mukherjee accounted for the differences in loading rate. Therefore, any conclusions that they drew from this data and the “stiffness” values reported by Dr. Gitis are neither reliable nor comparable. In fact, Dr. Gitis testified that if the sample load rates were different, it would “jeopardize the results” (Ex. PP, Gitis Dep. at 163:17).

## 2. Dr. Gitis’ Pliability Tests Are Scientifically Unreliable Because He Used the Wrong Diameter

18. In determining “stiffness,” Dr. Gitis assumed a monofilament circular structure. He also determined stiffness based on the moment of inertia, which is a function of the diameter raised to

the fourth power for a circular monofilament.<sup>1</sup> As I discussed in my previous report, I disagree with this assumption, but assuming that it is correct, it is important to use the correct diameters. This is because any error in the diameter between the treated and untreated samples results in an error in the “stiffness” values calculated by Dr. Gitis. It is my opinion that Dr. Gitis did not use accurate diameter measurements, and therefore, Dr. Gitis’ reported stiffness values are not scientifically acceptable.

19. I understand that Dr. Gitis used the same diameter for the treated and untreated FiberWire samples. That diameter was 0.65 mm (Gitis Report at 3). I understand from Dr. Gitis’ deposition that CETR measured the samples’ diameters with a caliper (Ex. PP, Gitis Dep. at 153:11-20). I am not able to fully review and analyze Dr. Gitis’ diameter measurements because he did record these measurements or the testing methodology (Ex. PP, Gitis Dep. at 174:7-10).

20. It is my opinion that Dr. Gitis’ measurements are inaccurate. Dr. Gitis’ diameter measurements contradict the measurements taken by Pearsalls. I have reviewed PR08456-57 (Ex. QQ). These documents show that Pearsalls measured the treated FiberWire’s average diameter as 0.586 mm and the untreated FiberWire’s average diameter as 0.600 mm. Therefore, Dr. Gitis’ measurements are different than Pearsalls’ measurements. In fact, Pearsalls measured the maximum diameter of the treated suture as 0.599 mm and the maximum diameter of the untreated suture as 0.635 mm., which are both less than the 0.65 mm diameter used by Dr. Gitis.

21. It is my opinion that Pearsalls uses a more accurate methodology for measuring diameter than Dr. Gitis. I understand that Pearsalls measures the diameter according to its TM36 procedure (Ex. JJ; Ex. RR; Ex. SS; Ex. TT, Hallett Dep. at 40:8-42:4; Ex. MM, Hallett Dep. at

---

<sup>1</sup> Dr. Gitis’ reported stiffness values also are dependent upon his assumption that the treated and untreated samples had a uniform circular cross-section. This not a correct assumption either.

174:12-20; 179:19-180:23; 185:4-9). Pearsalls' diameter measurement procedure (TM36) is stated to be performed according to the European pharmacopoeia (Ex. SS at PR8444). According to Pearsalls, the testing is accurate to 0.002 mm. (Ex. SS).

22. It is my opinion that Pearsalls' diameter measurement methodology is more accurate and scientifically reliable than using a caliper because it measures and keeps the transverse force constant. Dr. Gitis did not provide any information on whether he kept the transverse "crushing" force constant when he measured the sutures. Keeping the transverse "crushing" force constant is important because sutures are relatively compliant in transverse compression, indicating that they can deform during measurement and thereby yield inaccurate measurements. Because Dr. Gitis used a value (*i.e.*, 0.65 mm) that is higher than any valued measured by Pearsalls for the treated and untreated samples, obtained the same value for the treated and untreated samples, did not account for the "crushing" force, and used a caliper, it is my opinion that he did not use a scientifically reliable method for determining diameter.

### **3. The Stiffness Values Calculated By Dr. Gitis Were Not Performed With Scientifically Reliable Methods**

23. Dr. Gitis purports to determine the stiffness values in Table 1 of his report by using the relationship between modulus of elasticity and moment of inertia. As I understand his methodology, Dr. Gitis determined the stiffness values according to the formula  $(\text{slope}/(3.14 * D^2/4)) * D^4/64$ . This is mathematically equivalent to  $(\text{slope} * D^2)/16$ . He used a diameter of 0.65 mm, and the slope was purportedly determined from the data he obtained from his tests.

24. His calculations are based on the determination of the slope of the force v. strain curves. I tried to reproduce his calculations but was not able to obtain the same results that he lists in Table 1. Dr. Gitis did not state in his report how he calculated the slope.

At deposition, Dr. Gitis testified that he calculated the slope of the curves by taking the change in force after the preload was set to the completion of the test, and divided that by the strain between after the preload was applied and the end of the test (Ex. PP, Gitis Dep. at 187:8-15). Although this is not a scientifically acceptable methodology, it will work if the data is a straight line or the best fit through the data is essentially linear. My review of the data indicates that it essentially follows a straight line relationship. Thus, I determined the slope and the stiffness values as Dr. Gitis states that he did, but I did not generate the same stiffness values (Ex. UU). This means that Dr. Gitis did not determine slope as he stated in his deposition. I do not know what methodology he used to determine slope.

25. I also tried to determine Dr. Gitis' stiffness values by fitting a best straight line through the data following the pre-load and determining the slope of that curve. This is a scientifically acceptable method for determining slope. I used the TRENDLINE function, which produces a linear regression analysis, incorporated in MS Excel software to determine the slope of each data set and the  $R^2$  factor derived from each of the 16 sutures. I then multiplied each of the slope values by the diameter squared and divided it by 16, as Dr. Gitis suggested (Ex. PP, Gitis Dep. at 186:7-11).



The following table represents the pliability or stiffness for each of the 16 tested sutures using this method for determining slope.

	Treated, kg* m <sup>2</sup>	R <sup>2</sup>	Untreated, kg* m <sup>2</sup>	R <sup>2</sup>
1	8.71E-07	0.9974	7.50E-07	0.9936
2	3.74E-07	0.9883	7.23E-07	0.9983
3	6.17E-07	0.9936	9.17E-07	0.9980
4	3.58E-07	0.9915	7.49E-07	0.9955
5	2.81E-07	0.9904	5.35E-07	0.9831
6	4.28E-07	0.9891	1.00E-06	0.9766
7	3.99E-07	0.9984	1.04E-06	0.9958
8	3.40E-07	0.9906	8.24E-07	0.9976
Avg.	4.59E-07		8.18E-07	

As can be seen from this table, these pliability values are different than the ones reported in Dr. Gitis' report. Therefore, I do not understand what methodology Dr. Gitis used for determining slope and the "stiffness" values in Table 1 of his report. Because he has not shown what methodology he used, his methodology cannot be said to be scientifically acceptable.

26. I also note that Dr. Gitis' "pliability" test data details a parameter called "ZABS." I do not know what this parameter means, and Dr. Gitis was unable to explain what it means (Ex. PP, Gitis Dep. at 143:7-13). Thus, depending on what the parameter means, it may further affect my opinions.

**B. No Reliable Conclusions About Pliability Can Be Drawn From Dr. Gitis' "Pliability" Test Because The Results Are Contradicted By Dr. Gitis' Tissue Drag Test**

27. If the pliability test performed by Dr. Gitis is assumed to be reliable (it is my opinion that it is not) and the tissue drag test performed by Dr. Gitis is also assumed to be reliable (it is my opinion that it is not as described below), the "pliability" results from each test should be consistent. It is my opinion that the "pliability" results from each of these tests is not consistent and therefore no reliable conclusions about pliability can be drawn from Dr. Gitis' tests, even if

they were assumed to be proper tests. My analysis below assumes that the tissue drag test is a proper and reliable test. But it is not because the samples have differences other than coating, it incorrectly assumes a monofilament structure, it incorrectly assumes a circular cross section, it incorrectly assumes a constant diameter for all samples, and it assumes that the tissue-drag tests were done properly, which they were not.

28. The tissue drag test is described on page 12 of the CETR report. In the report, it is stated that a 20 mm length of suture was extended at a constant rate of 1 mm/sec while continuously recording the pulling force. Prior to the suture slipping, the test is similar to that specified in ASTM D2256-02 "Standard test method for tensile properties of yarn by the single strand method." Thus, putting aside the incorrect assumptions inherent in Dr. Gitis' tests and the flaws in the tissue drag tests (see below), prior to slipping between the leather pads, the recorded data can be used to determine the force/elongation relationship of the tested specimens.

29. I examined the data before slippage between the leather pads from the time period 0.1 to 0.5 seconds. This was to ensure that the time period of collected data was the same for each suture.

30. After examining the data, I plotted the individual force vs. strain data relationship for each of the eight coated and eight uncoated sutures. These plots are attached to this report as Ex. VV. I then used the TRENDLINE function incorporated in MS Excel software to determine the slope of each curve derived from each of the 16 sutures. These slopes represent the force on the thread line at a given time, or stated another way, force per unit time. Dr. Gitis reported that the specimens were originally 20 mm and the jaw moved at a constant rate of 1 mm/sec.

Accordingly, the strain rate on the specimen was 0.05 (mm/mm)/sec. I then divided the slope of each curve by 0.05/sec (the strain rate) and the assumed cross sectional area of each suture

(based on Dr. Gitis' assumed 0.65 mm) to obtain the tensile modulus. I then multiplied this value by the moment of inertia, based on Dr. Gitis' incorrect assumptions, to obtain the "pliability or stiffness" data for each suture. The following table represents the pliability or stiffness data for each of the 16 samples from the tissue drag test.

Specimen	Untreated, kg* m <sup>2</sup>	R <sup>2</sup>	Treated, kg* m <sup>2</sup>	R <sup>2</sup>
1	4.10E-07	0.9966	7.07E-07	0.9990
2	4.07E-07	0.9967	4.98E-07	0.9935
3	3.87E-07	0.9949	3.74E-07	0.9939
4	3.45E-07	0.9945	7.82E-07	0.9949
5	3.46E-07	0.9944	7.03E-07	0.9549
6	3.08E-07	0.9918	3.07E-07	0.9852
7	4.37E-07	0.9947	4.39E-07	0.9949
8	3.71E-07	0.9945	4.85E-07	0.9921
Avg.	3.76E-07		5.37E-07	

31. Based on this analysis, the tissue drag tests shows that the stiffness of the untreated suture was less than the stiffness of the treated suture. This contradicts what Dr. Gitis reported for his "pliability" test in Table 1 of his report where he reports that that the stiffness of the untreated suture was higher than the treated suture. Thus, even assuming his tests were done properly, no reliable conclusions can be drawn from them because the data from the tissue drag test contradicts the data from the "pliability" test.

**V. Dr. Gitis' Knot Slippage Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

32. It is my opinion that Dr. Gitis did not determine the knot slippage strength using a scientifically reliable testing methodology. According to Dr. Gitis report, his methodology is described on page 5 of his report. He states that the parallel rods were pulled apart at a constant velocity of 1 mm/sec. While the rods were pulled, CETR personnel measured and recorded the force until either the knot untied or 3 mm of slippage occurred. However, the tests were not conducted as stated in his report.

33. I examined the underlying data of the knot slippage test and Dr. Gitis' deposition testimony. According to Dr. Gitis, the Z column in the knot slippage data is the vertical displacement of rods (Ex. PP, Gitis Dep. at 230:12-14). Consequently, if the test was performed at a constant velocity as stated in the test report, the Z value should increase 1 mm every second. However, the data does not show this. In fact, the data shows that the displacement decreases with increasing time. At deposition, Dr. Gitis testified that the data was not consistent with a constant velocity of 1 mm/sec. (Ex. PP, Gitis Dep. at 246:9-12). Further, Dr. Gitis was not able to explain why the data showed that the Z value decreased (Ex. PP, Gitis Dep. at 245:13-19). Also, he could not fully explain what the data in the  $F_x$  and  $F_y$  columns represented (Ex. PP, Gitis Dep. at 229:16-20). Therefore, the test was not performed as reported, and the data is not explained. Based on the information provided, the testing methodology is not a scientifically acceptable test because there is no adequate explanation of the test methods or the data. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot slippage strength values are just data without meaning and context, and they cannot be scientifically relied upon.

#### **VI. Dr. Gitis' Knot Run-Down Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

34. It is my opinion that Dr. Gitis did not determine the knot run-down using a scientifically reliable test methodology. His methodology is partially described on page 7 of his report. However at deposition, Dr. Gitis could not fully describe the test methodology for this test. He testified that he did not know: (i) how the suture was attached to the upper brass rod (Ex. PP, Gitis Dep. at 236:3-9); and (ii) what he did with the lower end of the suture (Ex. PP, Gitis Dep. at 236:23-237:1). Dr. Gitis stated that he didn't remember how the test was conducted (Ex. PP, Gitis Dep. at 237:8-12). Thus, based on the information provided, the test, as described, is not a scientifically acceptable test because there is no adequate explanation of the test methods or how

the data was obtained. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot run-down values are just data without meaning and context, and they cannot be scientifically relied upon.

35. Although Dr. Gitis' knot-run down data is unreliable, even if were to be relied upon, it is inconclusive. Dr. Gitis' test results show in Table 3 that two of the treated samples had the same knot-run down force as two of the untreated samples. If coating has a material effect on knot run-down, then I do not understand why on two occasions the untreated samples had the same knot run-down force as two of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this (Ex. PP, Gitis Dep. at 218-226; Ex. WW, Mukherjee Dep. at 451:3-12). Absent an explanation, it is my further opinion that it is not scientifically reliable to conclude from the data that coating causes a smaller knot run-down force.

36. Also, I do not fully understand Dr. Gitis' knot run-down data because he could not explain it. He did not know what the data in the  $F_f$  column represented (Ex. PP, Gitis Dep. 241:10-11), and how the tests were conducted. Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

37. Further, I do not understand Dr. Gitis' methodology for reporting his data because the data he generated does not appear to correspond to the reported values in Table 3. For example, Dr. Gitis' data shows that coated sample 7 appeared to have the highest knot run-down peak force (Ex. XX, coated sample 7 denoted by blue unfilled circles). Yet, his reported data in Table 3 differs because coated sample 7 had a value of 0.19 kg., which was not the highest value reported in the chart. Dr. Gitis was not able to explain this difference (Ex. PP, Gitis Dep. at 242:16-243:4). Thus, I do not understand what methodology Dr. Gitis used, and his unknown methodology cannot be considered reliable.



**VII. Dr. Gitis' Friction Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained**

38. Dr. Gitis' friction tests are scientifically unreliable because the testing methodology was flawed, and there was no explanation of how the coefficient of friction was determined. Dr. Gitis' report partially describes the friction tests on page 9. According to Dr. Gitis, two sutures were each held in a suture holder by clamping one suture end and holding the other suture end by tightening a screw against the suture (Ex. PP, Gitis Dep. at 249:4-21). Dr. Gitis did not measure the clamping force (Ex. PP, Gitis Dep. at 249:22-24). Further, he did not measure the torque on the screw or the force placed on the suture by the screw (Ex. PP, Gitis Dep. at 249:25-250:2). Nor did he accurately control how tight the screw was placed against the suture (Ex. PP, Gitis Dep. at 250:16-252:9). Because Dr. Gitis' friction tests relies on rubbing two sutures against each other, the tension under which the sutures are subject to in the holder affects the measured friction parameters. Because Dr. Gitis did not use a scientifically reliable method to check the tension on the sutures in the suture holders, no scientific reliable conclusions can be drawn based on his friction tests.

39. Based on the information that was provided, Dr. Gitis' friction test methodology is also not scientifically reliable because he could not explain how his testing machine and software determined the coefficient of friction (Ex. PP, Gitis Dep. at 261:10-14; 263:14-265:6). Absent an explanation of how the friction coefficients were determined, they are values without any meaning, and they cannot be scientifically relied upon to determine the coefficient of friction.

40. Also, I do not fully understand Dr. Gitis' friction data because he could not explain it. He did not know what the  $F_f$  represented (Ex. PP, Gitis Dep. at 261:1-9). Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

**VIII. Dr. Gitis' Chatter Data Is Unreliable Because the Testing Methodology Is Not Known**

41. It is my opinion that Dr. Gitis' chatter data on page 11 of his report is not scientifically reliable because no explanation was provided as to how it was determined. Dr. Gitis provides a brief explanation on page 11 of his report but does not explain specifically how it was determined (*i.e.* he does not explain what "maximum and minimum" amplitudes were used and how they were used to generate the results from the friction and knot run-down tests). At his deposition, he was not able to explain how the chatter values were determined (Ex. PP, Gitis Dep. at 268:1-269:5). Therefore, absent an explanation of how the chatter values were determined, they are just values without any meaning, and they cannot be scientifically relied upon to draw conclusions.

42. Also, it appears that certain data related to Dr. Gitis' chatter determinations were not maintained by Dr. Gitis (Ex. PP, Gitis Dep. at 267:10-23). Since I did not have the opportunity to review the data, I cannot use it to understand whether Dr. Gitis used a scientifically acceptable method.

43. Further, Dr. Gitis' tests also show that one of the treated samples had about the same chatter value (0.012) as at least four of the untreated samples (0.013, 0.013, 0.012, 0.011), and another of the treated samples (0.010) had a value that was the same as at least one of the untreated samples (0.011). If coating had a material effect on chatter, then I do not understand why some of the untreated samples had the same chatter value as some of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this discrepancy (Ex. PP, Gitis Dep. at 269:22-270:2; Ex. WW, Mukherjee Dep. at 464:21-465:4). Based on these results, it is my further opinion that it is not scientifically reliable to conclude from the data that coating materially affects FiberWire's chatter.

**IX. Dr. Gitis' Tissue Drag Data Is Unreliable Because the Testing Methodology Is Flawed**

44. Dr. Gitis' tissue drag test involved dragging a suture through two pieces of leather that were clamped together. The results of the tissue drag test are a function of how tight the leather was clamped against the suture. If the force applied to the suture by the leather differed between samples, this will lead to different results that cannot be compared. Dr. Gitis clamped the leather together with a nut and bolt (Ex. PP, Gitis Dep. at 272:24-273:1). But Dr. Gitis did not control the force that was applied to the leather or how tightly the sutures were clamped between the leather (Ex. PP, Gitis Dep. at 273:2-5). Thus, because Dr. Gitis did not control the clamping force, he did not use a scientifically reliable methodology for performing the tissue-drag test, and it is not scientifically acceptable to compare the data he obtained between samples.

45. I also note that Dr. Gitis states in his report at page 12 that he conducted a second different tissue drag test with a needle. He did not provide any data or results from this test in his report or subsequent to his report. I understand that he no longer has the data (Ex. PP, Gitis Dep. at 271:10-272:9). Thus, I have not been provided the opportunity to assess this test or its results. It could be that this test contradicts his other tests, but I do not know because I have not seen the data.

46. Also, I note that Dr. Gitis' tissue drag data does not seem to correlate with his reported data. For example, his data shows that untreated sample 5 (magenta) had the highest static tissue-drag force (Ex. YY). But his report in table 6 shows that the highest static tissue-drag force for the untreated samples was sample no. 4. Dr. Gitis was not able to explain this discrepancy (Ex. PP, Gitis Dep. at 279:11-280:5). Thus, it is not clear what methodology Dr. Gitis used to obtain his reported tissue drag values. Therefore, for this additional reason, his unknown methodology cannot be considered scientifically reliable.

**X. Arthrex's Knot-Down Test Is Scientifically Unreliable For Assessing The Effects of FiberWire's Coating on FiberWire's Properties**

47. Dr. Mukherjee also relies on a "knot-tie down" test performed by Arthrex (Ex. 19 to Dr. Mukherjee's Responsive Report, see Mukherjee's Responsive Report at 24-25), which purportedly shows the effects of FiberWire's coating on knot tie-down properties. I am not aware of any documentation that establishes the construction and manufacturing processes that were used to construct the "uncoated" suture used in this test. Therefore, absent information about the construction and manufacturing of the tested samples, it is not possible to say that the only difference between the samples was coating. Further, it is scientifically unreliable to attribute the differences in the test results to coating.

48. I understand that Arthrex's counsel has indicated that the samples produced as ARM 25452 (DM Ex. 430) may be uncoated sutures from the same batch as that used in Arthrex's knot tie-down test. The sample designated as ARM25452 is white and does not have FiberWire's blue dye. I note that Mr. Grafton's email from July 2004 indicates that the "uncoated" samples used in Arthrex's knot-run down test were "removed from production before dying and coating" (Ex. ZZ). The sample and Mr. Grafton's email suggest that the untreated samples used in Arthrex's knot tie down test was not dyed, scoured, coated, stretched, or heated. Therefore, even if the sample known as ARM 25452 is the type that was tested by Arthrex, there is no scientific reliable method for making any conclusions about the materiality of the affects of FiberWire's coating on FiberWire's properties.

**XI. The FiberWire Photos Provided in Dr. Gitis' Report Do Not Show Coating**

49. Based on the information provided about the pictures shown in Dr. Gitis' report it, I cannot determine whether they show any coating. My opinion is supported by Dr. Gitis who stated that he could not see coating when he observed the samples under magnification (Ex. PP,

Gitis Dep. at 285:9-14). I understand that Dr. Mukherjee has opined that Figure 14 in Dr. Gitis' report shows coated sutures because the fibers are allegedly spaced closer together (Ex. WW, Mukherjee Dep. at 461:23-462:10). It is my opinion that this is not a scientifically acceptable analysis or conclusion. I understand from Dr. Gitis' and Dr. Mukherjee's testimony that it is not known what part of FiberWire is shown in the photos, and it is not known how exactly the material shown was handled (Ex. WW, Mukherjee Dep. at 462:12-18; Ex. PP, Gitis Dep. at 289:8-16). Thus, the spacing between the fibers could be a function of how the sutures were handled, cut, or clamped during the photos, as described by Dr. Gitis (Ex. PP, Gitis Dep. at 288:12-20). There is no reliable methodology provided by Dr. Mukherjee for opining that Figure 14 shows coating. I note that Dr. Gitis had other pictures taken but did not provide them for analysis (Ex. PP, Gitis Dep. at 286:7-17).

## **XII. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material**


50. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. AAA, Burks' Dep. at 87:7-13; 88:1-3; 96:18-19; 98:19-25). He also stated that he could not "clearly feel a difference" (Ex. AAA, Burks Dep. at 88:9-10). This supports my opinion that any purported differences are not material.

51. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (Ex. AAA, Burks Dep. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (Ex. AAA, Burks Dep. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (Ex. AAA, Burks. Dep. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in



surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 24, 2006

A handwritten signature in black ink, consisting of stylized, cursive letters, positioned above a horizontal line.

David Brookstein, Sc.D.  
Fellow-American Society of Mechanical Engineers

**CERTIFICATE OF SERVICE**

I certify that the foregoing Amended Supplemental Expert Report of Dr. David Brookstein was served in the manner indicated below on July 24, 2006 on the following:

*Via e-mail without exhibits and  
via Federal Express delivery (without exhibits)*  
Charles W. Saber  
Dickstein Shapiro LLP  
1825 Eye Street NW  
Washington D.C. 20006-5403  
saberc@dsmo.com

*Via Federal Express*  
Christopher Weld, Jr.  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109

Dated: July 24, 2006

  
\_\_\_\_\_  
Erich M. Falke

**Amended List of Additional Materials Considered**

Deposition Transcript of Mr. Lewis with exhibits  
Deposition Transcript of Mr. Hallet from June 30, 2006 with exhibits  
Steven B. Warner, *Fiber Science* 1995  
Deposition Transcript of Dr. Gitis with exhibits  
Deposition Transcript of Dr. Mukherjee with exhibits  
CETR Testing data  
Pearsalls documents 008433-008473  
CETR documents 0001-79  
FiberWire Samples Ex. 388, 390, 438, 429, 389, 428, 235, 236, 237  
Dr. Burks Transcript with exhibits  
“An Experimental Method for Determining the heat Transfer Coefficient of Polymeric Fibers and Yarns During Rapid Convective heating” by R. Brooks published in The Journal of the Textile Institute 1984, No. 6, I then pp. 398-404.  
DM. Ex 430  
DM. Ex. 433  
DM. Ex. 434  
ARM25591  
PR08325-08382  
TestWorks®4 “Continuing to set the standard for material, component, and subassembly testing software”  
Gordon Laboratory Seminar Series Lent 2006  
ASTM International, Designation: D 638-03, “Standard Test Method for Tensile Properties of Plastics”

# **EXHIBIT 15**

-----Original Message-----

**From:** Tamburo, Salvatore [mailto:TamburoS@dicksteinshapiro.com]  
**Sent:** Monday, July 24, 2006 6:17 PM  
**To:** Malinoski, Lynn A. (Woodcock Washburn); Bonella, Michael J. (Woodcock Washburn)  
**Cc:** Saber, Charles  
**Subject:** Dr. Gitis

Lynn and Mike:

Recently, it has come to our attention that Dr. Gitis's testing lab, CETR, was infiltrated by a software virus around the same time Dr. Gitis was conducting his tests of coated v. uncoated FiberWire and preparing his expert report based on those tests. Dr. Gitis conducted an investigation and has reason to believe that the actual test results included in his report may be based upon data that was corrupted due to the virus; however, Dr. Gitis cannot be certain whether the corruption occurred at the time the data was collected or when the report was generated. Dr. Gitis will be repeating his tests on additional samples of coated and uncoated FiberWire suture and preparing a new expert report. We plan to serve his new expert report as soon as possible and certainly within the next few weeks. After that, Dr. Gitis will be available for deposition with regard to his new expert report. We, of course, will afford Dr. Brookstein the opportunity to make further comments on Dr. Gitis's new report.

Regards,  
- Sal

**Sal Tamburo**  
Dickstein Shapiro LLP  
1825 Eye Street NW | Washington, DC 20006  
Tel (202) 420-5164 | Fax (202) 420-2201  
tamburos@dicksteinshapiro.com

-----  
This e-mail message and any attached files are confidential and are intended solely for the use of the addressee(s) named above. This communication may contain material protected by attorney-client, work product, or other privileges. If you are not the intended recipient or person responsible for delivering this confidential communication to the intended recipient, you have received this communication in error, and any review, use, dissemination, forwarding, printing, copying, or other distribution of this e-mail message and any attached files is strictly prohibited. Dickstein Shapiro reserves the right to monitor any communication that is created, received, or sent on its network. If you have received this confidential communication in error, please notify the sender immediately by reply e-mail message and permanently delete the original message.

To reply to our email administrator directly, send an email to [postmaster@dicksteinshapiro.com](mailto:postmaster@dicksteinshapiro.com)



# **EXHIBIT 16**



PHILADELPHIA OFFICE  
One Liberty Place, 46th Floor  
Philadelphia, PA 19103  
215.568.3100  
Fax: 215.568.3439

July 25, 2006

---

MICHAEL J. BONELLA  
PHILADELPHIA OFFICE  
215-564-8987  
bonella@woodcock.com

***Via Hand Delivery & Facsimile***

Salvatore Tamburo, Esq.  
Dickstein Shapiro Morin &  
Oshinsky LLP  
2101 L Street, N.W.  
Washington, D.C. 20037

**Re: DePuy Mitek, Inc. v. Arthrex, Inc. & Pearsalls, Inc.  
Case No. 04-12457 PBS**

Dear Sal:

Your July 24th allegations of an alleged virus, coming immediately after Dr. Brookstein's supplemental report was served, are surprising. They are further surprising because the produced CETR data do not appear to be corrupt at all.

Mitek does not agree that Dr. Gitis can supplement his report, create new reports, or conduct more testing. As an initial matter, regardless of any alleged "virus," Dr. Gitis' tests were not properly conducted, he did not test the correct samples, he did not know how the tests were conducted, he did not check the accuracy of his report when he wrote it, and he destroyed test data. Further, both Dr. Gitis and Dr. Mukhurjee admitted that neither of them were experts in interpreting the results of Dr. Gitis' tests. None of those issues relate to any so-called virus. Thus, regardless of any alleged virus, there is no legitimate reason for Dr. Gitis to conduct new tests, and Mitek will move to oppose any efforts by Dr. Gitis to supplement his report or to conduct tests.

Your correspondence states that Dr. Gitis report "may be based upon data that was corrupted" and he cannot be certain when the alleged corruption occurred. An allegation that his report "may" be based on corrupt data is not a reason for Dr. Gitis to reconduct his tests, much less to fix his many errors that have nothing whatsoever to do with any alleged virus. Notably, your correspondence does not provide any detail regarding the alleged virus/corruption or explain precisely how it allegedly affected the data in Dr. Gitis' report. Please provide more detail regarding the virus/corruption, produce the corrupt data, identify the alleged virus by name, identify the specific machines it allegedly infected, explain precisely what data are



Salvatore Tamburo, Esq.  
July 25, 2006  
Page 2

allegedly corrupt and how it affected Dr. Gitis' report, and provide all information in Dr. Gitis' and CETR's possession regarding this alleged virus, including any action taken by third-parties to address the virus.

If Dr. Gitis' report is based on corrupt data, Mitek expects that Arthrex will prove that to be the case, including the exact extent of the alleged corruption and when it occurred. If Arthrex and Pearsalls insist on this course of action and are permitted to do so by the Court, Mitek will conduct a full forensic investigation of Dr. Gitis' machines and computer systems with forensic and virus experts regarding this alleged virus. In the meantime, please immediately sequester the allegedly infected computers/machines, and other electronic records of this alleged virus and how it affected Dr. Gitis' work, so that Mitek can have forensic/virus experts analyze them, if that becomes necessary. Please confirm immediately that this has been done.

Sincerely,

A handwritten signature in black ink, appearing to read 'Michael J. Bonella', written over the printed name.

Michael J. Bonella

# **EXHIBIT 17**

-----Original Message-----

**From:** Saber, Charles [mailto:SaberC@dicksteinshapiro.com]

**Sent:** Tuesday, August 01, 2006 4:09 PM

**To:** Malinoski, Lynn A. (Woodcock Washburn); Bonella, Michael J. (Woodcock Washburn)

**Cc:** Tamburo, Salvatore

**Subject:** DePuy Mitek v. Arthrex

Lynn and Mike:

We just received word today that Dr. Gitis has an emergency that caused him to leave the country immediately for approximately three weeks. It appears that Dr. Gitis's absence will cause a delay in the testing, although we are trying to check to see if any delay can be avoided or lessened.

We will keep you advised of any further information that we receive.

Chuck

-----  
This e-mail message and any attached files are confidential and are intended solely for the use of the addressee(s) named above. This communication may contain material protected by attorney-client, work product, or other privileges. If you are not the intended recipient or person responsible for delivering this confidential communication to the intended recipient, you have received this communication in error, and any review, use, dissemination, forwarding, printing, copying, or other distribution of this e-mail message and any attached files is strictly prohibited. Dickstein Shapiro reserves the right to monitor any communication that is created, received, or sent on its network. If you have received this confidential communication in error, please notify the sender immediately by reply e-mail message and permanently delete the original message.

To reply to our email administrator directly, send an email to [postmaster@dicksteinshapiro.com](mailto:postmaster@dicksteinshapiro.com)

Dickstein Shapiro LLP

<http://www.DicksteinShapiro.com>

=====

8/2/2006

# **EXHIBIT 18**



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a )  
Massachusetts corporation, )  
Plaintiff, ) Civil Action  
vs. ) 04-12457 PBS  
ARTHREX, INC., a Delaware )  
corporation, )  
Defendant. )

- - - - -  
The deposition of DEBI PRASAD

MUKHERJEE was taken on Tuesday, June 13,  
2006, commencing at 9:08 a.m., at the  
offices of Dickstein Shapiro Morin &  
Oshinsky LLP, 2101 L Street, N.W.,  
Washington, D.C., before Susanne Bergling,  
Registered Merit Reporter and Notary Public.

<p style="text-align: right;">106</p> <p>1 generally speaking, the fewer throws, the better?</p> <p>2 A. That's correct.</p> <p>3 Q. Okay. Now, in your design -- your</p> <p>4 experience, did you do any work with heating and</p> <p>5 stretching materials in processing?</p> <p>6 A. Pardon me?</p> <p>7 Q. Did you do any work with heating and</p> <p>8 stretching materials during processing operations?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And what work did you do?</p> <p>11 A. Heating and what was the last --</p> <p>12 Q. Heating and stretching?</p> <p>13 MR. TAMBURO: Objection, vague.</p> <p>14 THE WITNESS: What is it?</p> <p>15 BY MR. BONELLA:</p> <p>16 Q. Stretch.</p> <p>17 A. Stretch? Yes, I do.</p> <p>18 Q. Okay. So, you did work with heating and</p> <p>19 stretching.</p> <p>20 A. Yes.</p> <p>21 Q. Did you do work with what's called hot</p> <p>22 stretching?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. What's the purpose of hot stretching</p> <p>25 material?</p>	<p style="text-align: right;">108</p> <p>1 THE WITNESS: Glass transition temperature</p> <p>2 and melting temperature.</p> <p>3 BY MR. BONELLA:</p> <p>4 Q. And why is a temperature selected between</p> <p>5 the glass transition temperature and the melting</p> <p>6 temperature for hot stretching operations?</p> <p>7 A. Because you want to orient the crystalline</p> <p>8 fraction by going up in glass transition rubbery</p> <p>9 region at the palm, so you can easily -- less far</p> <p>10 you can stretch, and then you don't want to --</p> <p>11 THE REPORTER: I'm sorry, I cannot</p> <p>12 understand what he is saying.</p> <p>13 THE WITNESS: Okay, let me repeat.</p> <p>14 THE REPORTER: Thank you.</p> <p>15 MR. TAMBURO: Slow down a little bit. It's</p> <p>16 okay.</p> <p>17 THE WITNESS: You go above glass transition</p> <p>18 temperature, you transfer the molecules from</p> <p>19 glassy state to the rubbery state, so you can</p> <p>20 stretch with less force. Then you don't go above</p> <p>21 melting point, because then you will melt the</p> <p>22 whole thing. That's the reason why you choose</p> <p>23 that temperature.</p> <p>24 BY MR. BONELLA:</p> <p>25 Q. So, hot stretching operations you say can</p>
<p style="text-align: right;">107</p> <p>1 A. The purpose is for --</p> <p>2 Q. For sutures.</p> <p>3 A. -- sutures, and they are different.</p> <p>4 Absorbable sutures, you want the in vivo strength</p> <p>5 up. In vivo means putting in the body. That's</p> <p>6 the most important thing. The polypropylene or</p> <p>7 Hytrel nonabsorbable is the handling properties,</p> <p>8 the surface properties.</p> <p>9 Q. What does hot stretching do to the surface</p> <p>10 properties of nonabsorbable sutures?</p> <p>11 A. It -- it makes it a little softer, so that</p> <p>12 the -- the fiber-against-fiber friction is</p> <p>13 reduced.</p> <p>14 Q. And what do you consider hot stretching to</p> <p>15 be?</p> <p>16 A. You apply some temperature and you stretch</p> <p>17 at the same time.</p> <p>18 Q. Were there any -- when you say a certain</p> <p>19 temperature, typically what type of temperature is</p> <p>20 selected for hot stretching?</p> <p>21 A. Yeah, usually between glass transition</p> <p>22 temperature and melting temperature, somewhere</p> <p>23 in --</p> <p>24 THE REPORTER: I'm sorry, I couldn't</p> <p>25 understand you.</p>	<p style="text-align: right;">109</p> <p>1 affect the handling properties?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. How about hot stretching, can it</p> <p>4 also affect strength properties?</p> <p>5 A. Yes.</p> <p>6 Q. Can hot stretching operations affect knot</p> <p>7 strength properties?</p> <p>8 MR. TAMBURO: Objection, vague.</p> <p>9 THE WITNESS: Let me ask you for</p> <p>10 clarification.</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. Sure.</p> <p>13 A. When you talk about knot strength, are you</p> <p>14 talking about the knot security or the knot</p> <p>15 sliding one strand over the other?</p> <p>16 Q. Well, let's talk about knot strength in</p> <p>17 terms of -- for today, can we use --</p> <p>18 A. Okay.</p> <p>19 Q. -- I think earlier we talked about knot</p> <p>20 strength, we talked about tying a knot in a suture</p> <p>21 and then applying a tension test and finding a</p> <p>22 point at which it breaks. Do you recall that?</p> <p>23 A. Right, right.</p> <p>24 Q. Can we call that knot strength?</p> <p>25 A. Okay, so from now on you're talking about</p>

<p style="text-align: right;">110</p> <p>1 knot strength being that, okay.</p> <p>2 Q. Okay. Now, can hot stretching operations</p> <p>3 affect the knot strength properties?</p> <p>4 A. Yes.</p> <p>5 Q. And how would they -- ho can they affect</p> <p>6 the knot strength properties?</p> <p>7 A. Generally, you don't want to decrease knot</p> <p>8 strength; usually increase the knot strength</p> <p>9 properties.</p> <p>10 Q. That's what you want to do?</p> <p>11 A. Yes.</p> <p>12 Q. And how do you achieve that through hot</p> <p>13 stretching, or do you -- I'm sorry, maybe I'm</p> <p>14 misunderstanding.</p> <p>15 How does hot -- can you explain or</p> <p>16 elaborate further how hot stretching affects the</p> <p>17 knot strength properties?</p> <p>18 A. You modify the surface brittleness so now</p> <p>19 the knot will slide easier, and therefore, these</p> <p>20 little microfibrils in these filaments will not</p> <p>21 break. So, therefore, the strength of the knot,</p> <p>22 after you put in, will increase.</p> <p>23 Q. Well, was one of ordinary skill in the art</p> <p>24 between 1988 and 1992 aware of what you've</p> <p>25 described with respect to hot stretching?</p>	<p style="text-align: right;">112</p> <p>1 Q. Okay. And how about the melting</p> <p>2 temperature of ultra high molecular weight</p> <p>3 polyethylene, would one of ordinary skill in the</p> <p>4 art have been able to figure that out between 1988</p> <p>5 and 1992?</p> <p>6 A. Yes.</p> <p>7 Q. And how hard would that have been to figure</p> <p>8 out?</p> <p>9 A. It's not hard.</p> <p>10 Q. Okay. Can the denier of yarns affect the</p> <p>11 knot strength?</p> <p>12 A. That's an open-ended question, the</p> <p>13 denier -- high denier or low denier or what you're</p> <p>14 talking about?</p> <p>15 Q. Right, any -- if you change the denier, can</p> <p>16 it affect knot strength, up, down?</p> <p>17 A. It can.</p> <p>18 Q. Okay. And how can the denier affect the</p> <p>19 knot strength?</p> <p>20 A. The reason I can say, if the denier is</p> <p>21 small per filament, let's say two denier per</p> <p>22 filament compared to six denier per filament, two</p> <p>23 denier per filament you've got more fibers into</p> <p>24 same diameter, so therefore, the knot strength is</p> <p>25 expected to go up, but that not always happen.</p>
<p style="text-align: right;">111</p> <p>1 A. Oh, yes.</p> <p>2 Q. Now, you said -- you referred to the glass</p> <p>3 transition temperature and melting temperature for</p> <p>4 materials, right?</p> <p>5 A. Yes.</p> <p>6 Q. Between 1988 and 1992, one of ordinary</p> <p>7 skill in the art could access those -- that glass</p> <p>8 transition temperature or the melting temperature</p> <p>9 for material by looking it up in a standard</p> <p>10 reference, right?</p> <p>11 A. Oh, yes.</p> <p>12 Q. What type of references would you look in?</p> <p>13 A. There are several polymer books, there are</p> <p>14 several encyclopedias, the literature, scientific</p> <p>15 literatures, biomaterials, a lot of other sources,</p> <p>16 textbooks.</p> <p>17 Q. Not a difficult thing to do, right?</p> <p>18 A. No.</p> <p>19 Q. Okay. How about for ultra high molecular</p> <p>20 weight polyethylene, between 1988 and 1992, would</p> <p>21 one of ordinary skill in the art have been able to</p> <p>22 obtain the glass transition temperature?</p> <p>23 A. Yes.</p> <p>24 Q. And how hard would that have been to do?</p> <p>25 A. It's not hard.</p>	<p style="text-align: right;">113</p> <p>1 There are a lot of processing details, a lot of</p> <p>2 information that go along with it.</p> <p>3 Q. Okay. How about the suture size, can that</p> <p>4 affect knot strength?</p> <p>5 A. Yes.</p> <p>6 MR. TAMBURO: Objection. Objection, vague.</p> <p>7 BY MR. BONELLA:</p> <p>8 Q. Okay. By "size," I'm talking about</p> <p>9 diameter.</p> <p>10 A. Yes.</p> <p>11 Q. A change in diameter.</p> <p>12 A. USP size, yeah.</p> <p>13 Q. Materials, can they affect knot strength?</p> <p>14 A. Sure.</p> <p>15 Q. How about picks per inch, can that affect</p> <p>16 knot strength?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Can the diameter affect the handling</p> <p>19 properties of a suture?</p> <p>20 A. Yes.</p> <p>21 Q. Can the diameter affect -- I'm sorry, can</p> <p>22 the materials selected for a suture affect the</p> <p>23 handling properties?</p> <p>24 A. Yes.</p> <p>25 Q. How about the denier, can that affect</p>

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
Civil Action No. 04-12457 PBS

---

DEPUY MITEK, INC., a Massachusetts	)
Corporation,	)
	)
Plaintiff,	)
	)
v.	)
ARTHREX, INC., a Delaware Corporation	)
	)
Defendant.	)

---

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

Page 422

1 but -- and, you know, you measure the strength of the  
 2 string whereas in bending, you do this way.  
 3 Q You do what way?  
 4 A And -- like you hold this and you bend.  
 5 You know, the forces go perpendicular to the direction  
 6 of the fiber. Now, nevertheless, this is what these  
 7 people have done. They know what technique they used  
 8 here.  
 9 Q Okay.  
 10 A I'm not really familiar with their  
 11 equipment, so -- their setup, so this person, Norm  
 12 Gitis, is the expert.  
 13 Q Okay.  
 14 A He's the person can answer all your  
 15 questions, how it was done and what tests that it was  
 16 used.  
 17 Q Okay. Now, the -- the bending test you  
 18 used, did you -- if I understand your testimony,  
 19 you're saying a tension test, normally a specimen is  
 20 loaded and you pull longitudinally on the specimen, is  
 21 that right?  
 22 A Right.  
 23 Q And you were saying a bending test,  
 24 normally you --  
 25 A You --

Page 423

1 Q -- perpendicular --  
 2 A -- bend it.  
 3 Q Transverse wise.  
 4 Do you know which way the specimen in the  
 5 pliability test that Dr. Gitis performed was loaded?  
 6 A I think it is a tensile test. That's what  
 7 he did.  
 8 Q You think he did a tensile test?  
 9 A That's my assumption. Norm Gitis is a  
 10 better person to tell you.  
 11 Q In a tension test, I think you said you  
 12 pull longitudinally one direction. But don't you  
 13 normally do it in two directions?  
 14 A No. Normally you do one direction.  
 15 Q In a tension test?  
 16 A Yes.  
 17 Q Why -- why did -- is -- why would -- why  
 18 is -- why is it -- why do you do a tension test here  
 19 then and call it a pliability test?  
 20 MR. TAMBURIO: Objection. The witness  
 21 already stated that he did not perform the tests and  
 22 he doesn't know the details about the tests and your  
 23 best person to ask is the person who did the tests,  
 24 the expert who did the tests, Norm Gitis. You're  
 25 welcome to ask your -- ask your questions, but he's

Page 424

1 already told you he doesn't know.  
 2 A This says -- in fact, you see the  
 3 reference was given.  
 4 BY MR. BONELLA:  
 5 Q Right.  
 6 A The Rodeheaver, they followed the  
 7 Rodeheaver's test. There's a reference to Rodeheaver,  
 8 and it's a published paper and the procedure is used  
 9 according to his paper. Again, Norman Gitis is the  
 10 person to answer your question.  
 11 Q Can you tell me why it was okay to use  
 12 this test for determine -- I'm sorry.  
 13 Can you tell me why it was okay to use the  
 14 pliability tests that Dr. Gitis used to determine  
 15 pliability for FiberWire?  
 16 MR. TAMBURIO: Same objection. The witness  
 17 is not an expert in these test procedures, and he's  
 18 already told you that the person to speak with is Norm  
 19 Gitis. To the extent you know the answer, you can  
 20 answer.  
 21 A I answered your question before.  
 22 BY MR. BONELLA:  
 23 Q What is your answer?  
 24 A That I do not know.  
 25 Q Okay. Did you approve the pliability

Page 425

1 tests that he -- that he did? I'm sorry, I'll ask you  
 2 that question. Did you approve the pliability tests  
 3 that Dr. Gitis did before he did it?  
 4 MR. TAMBURIO: Objection, vague.  
 5 A He's the authority. He decided on it  
 6 and -- and we just did the -- we didn't measure  
 7 pliability, all right? That is the extent of  
 8 conversation I had. He decided the procedure and the  
 9 technique.  
 10 (Exhibit No. 363 was marked.)  
 11 BY MR. BONELLA:  
 12 Q Okay. I'll show you DePuy Mitek  
 13 Exhibit 363 -- it's Bates numbers CETR42 through 47 --  
 14 and ask you if you recognize the e-mail chain in  
 15 Exhibit 363.  
 16 A Yes, I do.  
 17 Q Okay. And is the DMUKH@earthlink.net  
 18 address, is that your e-mail address?  
 19 A KHE. There's no E there. DMUKHE at  
 20 Earthlink.  
 21 Q What is your e-mail address?  
 22 A DMUKHE, but it doesn't have an E there.  
 23 Q Doesn't have an E? Right.  
 24 A Because there is no E there.  
 25 Q Right. Well, what is your e-mail? Your

3 (Pages 422 to 425)

# **EXHIBIT 19**



IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS

-----x  
DEPUY MITEK INC., a :  
Massachusetts Corporation, :  
Plaintiff, :  
vs. : Civil Action No.  
ARTHREX, INC., a Delaware : 04-12457  
Corporation, and PEARSALLS :  
LIMITED, a Private Limited :  
Company of the United :  
Kingdom, :  
Defendants. :  
-----x

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by  
counsel for the Plaintiff, pursuant to notice,  
commencing at 8:15 a.m., at the law offices of  
Dickstein Shapiro Morin & Oshinsky LLP, 2101 L  
Street, Northwest, Washington, D.C., before  
Dawn A. Jaques, Certified Shorthand Reporter  
and Notary Public in and for the District of  
Columbia, when were present on behalf of the  
respective parties:

<p>82</p> <p>1 Q. Thank you. The testing that you did in 2 connection with this case in your reports, who 3 actually did the testing?</p> <p>4 A. I did it together with two engineers in 5 my lab.</p> <p>6 Q. Okay. And what engineers?</p> <p>7 A. Michael Vinogradov and Vishal Khosla.</p> <p>8 Q. Can you spell their names, please?</p> <p>9 A. Michael V-I-N-O-G-R-A-D-O-V, Vinogradov, 10 and Vishal K-H-O-S-L-A, Khosla. One is from 11 Russia, one is from India.</p> <p>12 Q. I'm going to guess Mr. Vinogradov is 13 from Russia?</p> <p>14 A. Good guess.</p> <p>15 Q. What did Mr. Vinogradov do with respect 16 to the test? What was his role?</p> <p>17 A. He helped to set up the testers and 18 modules, and he did some of the tests together 19 with me.</p> <p>20 Q. What tests did Mr. Vinogradov do?</p> <p>21 A. Most of the tests, or maybe all of the 22 tests we kind of did together.</p> <p>23 Q. So Mr. Vinogradov was involved in all 24 the tests?</p> <p>25 A. Yeah, and same thing with Mr. Khosla.</p>	<p>84</p> <p>1 running, most of these tests took less than a 2 minute, right, actual running time?</p> <p>3 A. Not really. Depends on what you call 4 the running. You have to set up the specimen, and 5 for some of them you have to make notes, so most 6 of them took several minutes. So, yeah, I was in 7 and out of the room during this test.</p> <p>8 Q. And what percentage of the test did you 9 actually see?</p> <p>10 A. Maybe between 25 and 50 percent.</p> <p>11 Q. Okay. Is there any of the tests that 12 you didn't actually witness the test being done of 13 the tests that were done? Let me ask a better 14 question.</p> <p>15 There's pliability tests that you've 16 described. Were you present for at least some of 17 the actual testing of the pliability samples for 18 pliability?</p> <p>19 A. Yes, I was present in at least some of 20 each and every test, each type of test.</p> <p>21 Q. Okay. So you weren't present the whole 22 time for this set-up and loading of each sample; 23 is that right?</p> <p>24 A. That's correct.</p> <p>25 Q. And from the tests that were done, data</p>
<p>83</p> <p>1 Q. How did their roles, Mr. Vinogradov and 2 Mr. Khosla's roles, differ?</p> <p>3 A. Vinogradov is a more senior member of 4 the team, and he was involved fully in all the 5 tests that we did for Ethicon and U.S. Surgical, 6 and he was the only one who remembered something 7 from those old tests.</p> <p>8 So Michael was more senior. He was 9 helping mostly in setting up the tests, and Vishal 10 was helping mostly in running the tests, and I was 11 like in and out. I was not there hundred percent 12 of the time.</p> <p>13 Q. Okay. You weren't there 100 percent of 14 the time for the set-ups; is that right?</p> <p>15 A. For all of it, for the set-ups and the 16 test. So they will do the set-up, I would come 17 approve or not approve, and then we would start 18 running tests. I would come out, come back and 19 see what is happening.</p> <p>20 Q. Did you approve each set-up after it was 21 done before the test was run?</p> <p>22 A. Yeah, of course.</p> <p>23 Q. You visually looked at each set-up?</p> <p>24 A. Yes.</p> <p>25 Q. And in terms of when the tests were</p>	<p>85</p> <p>1 was generated, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And all the data that was 4 generated, was that computer generated?</p> <p>5 A. Yes.</p> <p>6 Q. And then from the computer-generated 7 data, some calculations and results were 8 presented?</p> <p>9 A. Yes.</p> <p>10 Q. Who did the calculations?</p> <p>11 A. Two of them, Michael and Vishal.</p> <p>12 Q. Okay. What was your involvement in the 13 calculations?</p> <p>14 A. We discussed the formula used, and I 15 checked the results.</p> <p>16 Q. Did you check every result, or just kind 17 of spot check it?</p> <p>18 A. I checked most of the results.</p> <p>19 Q. Okay. Did you instruct Mr. Vinogradov 20 and Mr. Khosla as to how to -- as to what formulas 21 to use and how to generate the results from the 22 data?</p> <p>23 A. How to generate results, I don't have to 24 instruct them. They know how to do it.</p> <p>25 What formula to use, maybe it was not my</p>

<p>150</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And then the second, is Z a zero?</p> <p>4 A. Yes.</p> <p>5 Q. Does that tell you this is where the</p> <p>6 test started after the preload was applied?</p> <p>7 A. I'm sorry, I have to think much more how</p> <p>8 to read this raw data.</p> <p>9 Q. Have you read the raw data before today</p> <p>10 that was used for the test?</p> <p>11 A. In my life? For this testing? No.</p> <p>12 Q. No, okay.</p> <p>13 A. I was looking only at the results.</p> <p>14 Q. Okay. Do you see the force column?</p> <p>15 A. Yes.</p> <p>16 Q. And at the time, .504 -- the force being</p> <p>17 applied to the specimen is .55 kilograms, right?</p> <p>18 A. Yes.</p> <p>19 Q. In your paper, in your page 3 --</p> <p>20 A. Yes.</p> <p>21 Q. -- of your report, you say the suture</p> <p>22 was preloaded with a tension of .5 kilograms.</p> <p>23 Preloaded suture was then pulled at a force,</p> <p>24 uniformly increasing at a rate of .33 kilograms</p> <p>25 per second.</p>	<p>152</p> <p>1 Q. And how is that controlled by the</p> <p>2 machine?</p> <p>3 A. It is the same servo-control as we</p> <p>4 discussed before.</p> <p>5 Q. It's measuring the force applied?</p> <p>6 A. Yes.</p> <p>7 Q. And it's programmed into it to increase</p> <p>8 it?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So the column F sub Z, after the</p> <p>11 preload was applied, should that be going up at a</p> <p>12 rate of .33 kilograms per second?</p> <p>13 A. Yes.</p> <p>14 Q. What we're going to do is we have a CD</p> <p>15 with the data on it, if that's easier for you to</p> <p>16 look at.</p> <p>17 A. Yeah, it will be much easier.</p> <p>18 Q. It's Bates number ARM 25902. It's</p> <p>19 entitled CETR Raw Data.</p> <p>20 Do you have a later flight option?</p> <p>21 A. I thought we already finished.</p> <p>22 Q. Not quite.</p> <p>23 A. Go on with the rest of your questions.</p> <p>24 Q. Let me ask you while he's loading that</p> <p>25 up, I'll ask you a question. Page 3 at the top</p>
<p>151</p> <p>1 A. Yes.</p> <p>2 Q. Now, the uniform increase in rate you're</p> <p>3 talking about, is that uniform increase in the</p> <p>4 load that's applied to the specimen?</p> <p>5 A. Yes.</p> <p>6 Q. So you applied a .5 kilogram preload to</p> <p>7 specimen, right?</p> <p>8 A. Yes.</p> <p>9 Q. And then you increase that .5 kilogram</p> <p>10 preload at a rate of .33 kilograms per second</p> <p>11 uniformly, right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. So at time --</p> <p>14 A. Uniform in time, yeah.</p> <p>15 Q. So at, say when the actual -- after the</p> <p>16 preload is applied, if you call that time zero,</p> <p>17 after the first second, the load applied should be</p> <p>18 .5 --</p> <p>19 A. Plus .33.</p> <p>20 Q. Would be .83?</p> <p>21 A. Yes.</p> <p>22 Q. And then it goes up?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. And it goes up uniformly, so for each --</p> <p>25 A. Yes.</p>	<p>153</p> <p>1 you say the suture of 50 millimeters in length.</p> <p>2 A. Yes.</p> <p>3 Q. So you used a 50 millimeter gauge line</p> <p>4 for each sample?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. What device did you use to</p> <p>7 measure the gauge lines?</p> <p>8 A. Caliper.</p> <p>9 Q. Caliper?</p> <p>10 A. Yeah.</p> <p>11 Q. Okay. And the diameter you say is .65</p> <p>12 millimeters.</p> <p>13 A. Measured this by caliper.</p> <p>14 Q. Did you measure the diameters?</p> <p>15 A. Yes.</p> <p>16 Q. Of each sample?</p> <p>17 A. Yes.</p> <p>18 Q. Every sample?</p> <p>19 A. Not every sample, but we measured it at</p> <p>20 least 10, 12 times, yeah.</p> <p>21 Q. And you always got .65 millimeters?</p> <p>22 A. Pardon me?</p> <p>23 Q. And you always got .65 millimeters?</p> <p>24 A. Yes.</p> <p>25 Q. For each sample?</p>

<p style="text-align: right;">154</p> <p>1 A. Yes.</p> <p>2 Q. So the coated and uncoated, did you</p> <p>3 measure the diameter?</p> <p>4 A. Yes.</p> <p>5 Q. And they were the same?</p> <p>6 A. Yes.</p> <p>7 Q. No difference?</p> <p>8 A. No difference as measured with a</p> <p>9 caliper.</p> <p>10 Q. Okay. I'm going to show you -- here's</p> <p>11 the computer. I think that your data is in files,</p> <p>12 and there's one that says "Modulus Raw Plots." Do</p> <p>13 you see that? I believe that's your --</p> <p>14 A. Yeah.</p> <p>15 Q. If you could open up that file of the</p> <p>16 modulus raw plots file. I think that's what we're</p> <p>17 looking at here. Is this coated or uncoated, or</p> <p>18 is it both?</p> <p>19 A. No, it seems to be opening. Hopefully</p> <p>20 it will open.</p> <p>21 Q. That's the uncoated graph, right?</p> <p>22 A. Maybe I will reduce magnification.</p> <p>23 Yeah.</p> <p>24 Q. Can you find -- we were looking at the</p> <p>25 printouts of the coated. Can you find the coated</p>	<p style="text-align: right;">156</p> <p>1 explain for a second -- I'm sorry, did you ask me</p> <p>2 a question, why it's every time 10.04 or 10.05 or</p> <p>3 10.06?</p> <p>4 Q. No.</p> <p>5 A. Because of its servo-control, so it</p> <p>6 always measures the real time. It says go for 10</p> <p>7 seconds, but it measures with the accuracy of</p> <p>8 hundredths of a second, so every time it's 10.06,</p> <p>9 10.05, 10.04. Every time it's slightly different.</p> <p>10 Q. I'm just going to move it over.</p> <p>11 A. Yeah, sure, sure.</p> <p>12 Q. What's going on here?</p> <p>13 A. I don't know what Erich did to it.</p> <p>14 Q. Now we're all the way on the left-hand</p> <p>15 side. See it says radius minus 13.136, 10.05.</p> <p>16 Looks like that's in the third column, right?</p> <p>17 A. Yeah, perfect. This is what we see now,</p> <p>18 right?</p> <p>19 Q. I don't know that we're seeing all the</p> <p>20 digits in the spreadsheet. Is there more digits</p> <p>21 in there?</p> <p>22 A. Maybe if we increase the width of the</p> <p>23 column. Yeah, now we see.</p> <p>24 Q. So, for example, if this is Sample 2,</p> <p>25 the test is actually starting at line 4694.</p>
<p style="text-align: right;">155</p> <p>1 in that file?</p> <p>2 Okay, there's the graph for the coated,</p> <p>3 right? Okay. Now, if you go to the data for the</p> <p>4 coated that we were looking at on the printouts,</p> <p>5 there's the data, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And we're looking at here part</p> <p>8 way down. If you go all the way to the top, right</p> <p>9 there, that is the top, this is the setting of the</p> <p>10 preload, right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, could you go down and find</p> <p>13 where the preload stops and the test, if you will,</p> <p>14 if you want to call it that, the test part of it</p> <p>15 begins?</p> <p>16 A. Okay, one sec. I was there, and I just</p> <p>17 lost it. Erich, we need you, only your hands can</p> <p>18 work with this. I just saw it a second ago.</p> <p>19 Q. So that's where the actual --</p> <p>20 A. You'll see 10 seconds. 10 seconds were</p> <p>21 over, and preload was over. I'm looking at time.</p> <p>22 Q. Right. And -- okay. I see on the</p> <p>23 printout, see, for example, on column 2 it says</p> <p>24 No. 2, radius, velocity, duration?</p> <p>25 A. Because you know what, because I will</p>	<p style="text-align: right;">157</p> <p>1 A. Right.</p> <p>2 Q. Right, which would be this line here for</p> <p>3 Sample 2, see how it matches up 0.5, 13.629,</p> <p>4 30.3790. See that?</p> <p>5 A. Yeah.</p> <p>6 (DePuy Mitek Exhibit No. 396 was marked</p> <p>7 for identification.)</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. Okay. I'm going to mark 396 as this</p> <p>10 page where it looks like the preload had finished</p> <p>11 and the testing is starting for at least</p> <p>12 Samples 1, 2 and 3. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So let's just look at Sample 2.</p> <p>15 Sample 2 at time zero, right --</p> <p>16 A. Yes.</p> <p>17 Q. -- the load is .5?</p> <p>18 A. Yes.</p> <p>19 Q. And time zero is measured in seconds,</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And you said the load is going up .33</p> <p>23 uniformly per second?</p> <p>24 A. Yes.</p> <p>25 Q. So at time T equals 1, the load should</p>

<p style="text-align: right;">162</p> <p>1 A. Yes.</p> <p>2 Q. Is there an assumption in the test that</p> <p>3 it's a uniform increase in --</p> <p>4 A. Yes.</p> <p>5 Q. And that assumption is wrong?</p> <p>6 A. No, I didn't say so.</p> <p>7 Q. I didn't say you did. I said if the</p> <p>8 assumption is wrong, how does that -- what does</p> <p>9 that do to the results?</p> <p>10 A. It would have no result -- no effect on</p> <p>11 the results.</p> <p>12 Q. Even if it wasn't uniform?</p> <p>13 A. Yes.</p> <p>14 Q. Why is that?</p> <p>15 A. Because we loaded sutures uniformly or</p> <p>16 not, whether we loaded with -- at the rate of .3</p> <p>17 kilogram per second or .03 kilogram per second, we</p> <p>18 saw clear differences between coated and uncoated,</p> <p>19 clear repeatable statistically different results</p> <p>20 for coated and uncoated sutures.</p> <p>21 Q. If you didn't load them uniformly,</p> <p>22 right, each one was loaded at a different rate --</p> <p>23 A. Yes.</p> <p>24 Q. -- you would generate different strains</p> <p>25 per time, right?</p>	<p style="text-align: right;">164</p> <p>1 Q. Yeah. You assumed that the diameter was</p> <p>2 constant along those lengths?</p> <p>3 A. No, we didn't make this assumption.</p> <p>4 Q. You didn't?</p> <p>5 A. No.</p> <p>6 Q. Well, you used -- did you use 0.65</p> <p>7 millimeters in calculating all the stiffness data</p> <p>8 that's presented in Table 2?</p> <p>9 A. Yes.</p> <p>10 Q. So did you actually measure along every</p> <p>11 point of the length of every suture?</p> <p>12 A. No.</p> <p>13 Q. Okay. So you did some measurements?</p> <p>14 A. We assumed that this data is the average</p> <p>15 diameter, but we did not assume -- we did not make</p> <p>16 any assumptions on each cylinder being ideally --</p> <p>17 ideally cylindrical because nothing is ideal in</p> <p>18 this life.</p> <p>19 If you want to characterize cross</p> <p>20 section of the cylinder, you have to deal with</p> <p>21 average parameters for the cylinder.</p> <p>22 Q. Well, doesn't the test assume that</p> <p>23 applying a -- you measured diameters along the</p> <p>24 length of some specimens for the pliability tests?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">163</p> <p>1 A. Yes.</p> <p>2 Q. So the graphs that generated would not</p> <p>3 be correct?</p> <p>4 A. No, the graphs would still stay because</p> <p>5 this graph is just one column versus another</p> <p>6 column. You have column -- we just looked with</p> <p>7 you at the computer. You have column force, and</p> <p>8 you have column strain, and you just plot force</p> <p>9 versus strain or strain versus force, and whether</p> <p>10 it was increasing uniformly or not, it cannot</p> <p>11 change this graph.</p> <p>12 Q. Let me ask you a different question. If</p> <p>13 the loads didn't increase at a uniform rate, at</p> <p>14 the same uniform rate on each sample, you can't</p> <p>15 really compare the graphs to each other?</p> <p>16 A. If for every sample the rates were</p> <p>17 different, it would jeopardize the results.</p> <p>18 Q. Okay. You assumed in this test that the</p> <p>19 diameter was constant along the length of each</p> <p>20 specimen, right?</p> <p>21 A. I didn't understand your question.</p> <p>22 Q. Each specimen, for the pliability test,</p> <p>23 you assumed that the diameter --</p> <p>24 A. We recall specimens at 50 millimeter</p> <p>25 from the suture.</p>	<p style="text-align: right;">165</p> <p>1 Q. And you calculated an average diameter?</p> <p>2 A. This is what we planned to do, but we</p> <p>3 didn't have to do it because many measurements</p> <p>4 that we did produced the same result, .65.</p> <p>5 Q. Who measured the diameter?</p> <p>6 A. Michael Vinogradov.</p> <p>7 Q. How much experience does he have in</p> <p>8 measuring suture diameters?</p> <p>9 A. In measuring suture diameters, his</p> <p>10 experience is very, very limited, but in measuring</p> <p>11 diameters of cylinders, he has plenty of</p> <p>12 experience.</p> <p>13 Q. How about in measuring diameter of</p> <p>14 specimens on the order of the size of a suture?</p> <p>15 A. We have lots of experience for this.</p> <p>16 Q. No, him personally.</p> <p>17 A. Him personally.</p> <p>18 Q. Does the device that you used to measure</p> <p>19 diameter, specifically what was the device used?</p> <p>20 A. Caliper.</p> <p>21 Q. What's the type and name of the caliper?</p> <p>22 A. Made by a Japanese company called</p> <p>23 Mitutoyo, but I don't remember the particular</p> <p>24 model.</p> <p>25 Q. Was it digital or --</p>

<p style="text-align: right;">170</p> <p>1 Q. Okay. Can you explain why there would 2 be a difference if this applies to the same 3 suture?</p> <p>4 MR. TAMBURRO: Objection, calls for 5 speculation.</p> <p>6 THE WITNESS: I cannot explain. I don't 7 know --</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. And you agree that the .65 that you used 10 is above the maximum that was measured at least 11 for this sample in Exhibit 399?</p> <p>12 A. Yes.</p> <p>13 Q. If you look at Exhibit 400, for the 14 uncoated the diameter average was .600 15 millimeters, the min was .570, and the max was 16 .635. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And so for this uncoated sample in 19 Exhibit 400, the maximum diameter that was 20 measured is less than the diameter that you used, 21 right?</p> <p>22 A. Yes.</p> <p>23 Q. Can you explain that?</p> <p>24 A. No, I cannot.</p> <p>25 Q. And do you see how the uncoated in</p>	<p style="text-align: right;">172</p> <p>1 the deposition of Dr. Mukherjee or from some 2 rebuttal or report of Dr. -- of your expert 3 witness.</p> <p>4 Q. I'll show you the next exhibit.</p> <p>5 THE VIDEOGRAPHER: I need to change. It 6 takes 20 seconds.</p> <p>7 MR. BONELLA: That's all right, keep 8 going.</p> <p>9 (DePuy Mitek Exhibit No. 401 was marked 10 for identification.)</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. DePuy Mitek Exhibit 401 -- I'm sorry, I 13 labeled the inside page, but it's a 4-page 14 document. Part of it is not from the same 15 document, but the last page is suture size and 16 diameter chart. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 MR. TAMBURRO: I'm sorry, are you 19 representing this as a USP chart?</p> <p>20 MR. BONELLA: The last page is.</p> <p>21 MR. TAMBURRO: The last page is.</p> <p>22 BY MR. BONELLA:</p> <p>23 Q. Okay, if you go to -- one column says 24 non-absorbable and synthetic absorbable sutures, 25 and there's a number 2. Do you see that?</p>
<p style="text-align: right;">171</p> <p>1 Exhibit 400 and the coated in 399 had different 2 measurements for average/minimum/maximum 3 diameters?</p> <p>4 A. Yes -- no. I see the same minimums, but 5 different averages and maximums.</p> <p>6 Q. Yes, I'm sorry, thank you. But didn't 7 find any difference in the diameters when you 8 measured them?</p> <p>9 MR. TAMBURRO: Objection, 10 mischaracterizes testimony.</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. I'm sorry, did you find differences in 13 diameters between the coated and uncoated samples 14 that you tested in the pliability tests?</p> <p>15 A. We specifically looked for it, and we 16 didn't find the differences.</p> <p>17 Q. Okay. Now, are you familiar with the 18 USP sizing for diameters?</p> <p>19 A. No, I am not.</p> <p>20 Q. Okay. Are you familiar with a No. 2 21 designation for suture?</p> <p>22 A. No.</p> <p>23 Q. Did you ever hear of a diameter range 24 for a No. 2 suture?</p> <p>25 A. No. Maybe I heard about it either from</p>	<p style="text-align: right;">173</p> <p>1 A. Yes.</p> <p>2 Q. And it has diameter limits of .5000 to 3 .599 for that. Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And the diameter you used of .655 is 6 above those diameter limits, right?</p> <p>7 A. Yes.</p> <p>8 Q. Did you test any sutures other than 9 No. 2 size suture?</p> <p>10 A. I did not test any sutures rather than 11 those spools I received from the law firm.</p> <p>12 Q. If the diameter of the coated and 13 uncoated were different, that would change the 14 pliability test data stiffness that's presented in 15 table -- on page 4 of your report, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay, you want to break for lunch?</p> <p>18 MR. TAMBURRO: Sure.</p> <p>19 THE VIDEOGRAPHER: This is the end of 20 Tape 2, beginning of Tape 3. Off the record at 21 12:45:46.</p> <p>22 (Lunch break taken.)</p> <p>23 THE VIDEOGRAPHER: This is the beginning 24 of Tape 3 in the deposition of Dr. Norm V. Gitis. 25 On the record -- excuse me, can we go off the</p>



<p>174</p> <p>1 record? Off the record at 1:43:13.  2 (Pause in the proceedings.)  3 THE VIDEOGRAPHER: This is Tape 3 in the  4 deposition of Dr. Norm V. Gitis. On the record at  5 1:44:58.  6 BY MR. BONELLA:  7 Q. Were there any recordation of the  8 diameter measurements that you said were made? Is  9 there anywhere that was recorded?  10 A. No, it was not.  11 Q. According to the data, it shows for the  12 pliability tests that you had eight samples of  13 coated and uncoated that were reported in tests?  14 A. Yes.  15 Q. Okay. Other than the eight, did you do  16 any other samples that aren't recorded there?  17 A. No.  18 Q. Why did you choose eight?  19 A. Because among the references we cited,  20 some people tested five, some seven, some ten, so  21 we saw eight as somewhere in the middle.  22 Q. Okay. Any other reason?  23 A. Huh?  24 Q. Any other reason?  25 A. That's about it.</p>	<p>176</p> <p>1 A. No.  2 Q. You just orally told him?  3 A. Yes.  4 Q. Okay. And do you know how you arrived  5 at the .33 kilogram per second?  6 A. It was from some -- again, from the same  7 references. From one of the references cited.  8 Q. Either the --  9 A. 'Rodeheaver or --  10 Q. Bizwada patent?  11 A. Yeah.  12 Q. So this pliability test is actually --  13 the test you did is actually a tension test, isn't  14 it?  15 A. It's a pliability test.  16 Q. It's also a tension test, right?  17 A. Yes.  18 Q. And in order for it to be a pliability  19 test, certain assumptions have to be true, right?  20 A. Yes.  21 Q. Is one of the assumptions that the  22 compressive and tensile modulus of the specimen --  23 let me rephrase that.  24 Is one of the assumptions that the  25 compressive and tensile moduli are the same for</p>
<p>175</p> <p>1 Q. Who actually wrote this report?  2 A. I did.  3 Q. You did? So you put the 0.33 kilogram  4 per second uniform increase in?  5 A. Yes.  6 Q. Where did you get that from?  7 A. From my engineers. They gave me the  8 number.  9 Q. You got that from them?  10 A. Yeah.  11 Q. Did you program yourself, did you put  12 into the machine the rate at which the load should  13 go up?  14 A. No, I did not.  15 Q. Do you have any documents where you  16 specified the parameters for the test that should  17 be inputted into the machine?  18 A. Yes. If it's not provided in the Excel  19 files -- what documents do you mean?  20 Q. Like, for example, if you wrote, either  21 typed up or handwritten, said to your assistant,  22 said, okay, the pliability tests, here is how I  23 want you to run it, 50 centimeter gauge length,  24 uniform increase of load at this rate, preload of  25 this. Did you make some kind of document?</p>	<p>177</p> <p>1 the specimen?  2 A. It was not specifically the assumption  3 for this test.  4 Q. You didn't assume that one way or the  5 other?  6 A. No, we did not.  7 Q. You didn't consider it?  8 A. Again, as we discussed before lunch, we  9 just decided to use the same test as our  10 customers.  11 Q. So you didn't use -- you didn't consider  12 whether that was an assumption that goes into  13 applying this test for stiffness then?  14 MR. TAMBURRO: Objection, vague.  15 THE WITNESS: No, we did not spend much  16 time on considering assumptions of our customers.  17 BY MR. BONELLA:  18 Q. If the compressive and tensile moduli  19 for the FiberWire specimens you tested are not the  20 same, how would it affect the pliability test  21 results that you've prepared?  22 A. It's hard to say. Depends on their  23 levels.  24 Q. If they're different, if the compressive  25 and tensile moduli for the FiberWire samples are</p>

<p style="text-align: right;">194</p> <p>1 and decided that this range is good.</p> <p>2 Q Look at the graphs on 382. It looks</p> <p>3 like some of the graphs -- some of the samples you</p> <p>4 stopped before others. Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Why is that?</p> <p>7 A I don't remember.</p> <p>8 Q Is that where you actually stopped?</p> <p>9 A Yeah.</p> <p>10 Q At the end of the pliability test data</p> <p>11 in your report, Exhibit 381, after the chart --</p> <p>12 A Yes.</p> <p>13 Q -- down here you say the stiffness of</p> <p>14 the coated sutures was found to be lower than that</p> <p>15 of the uncoated sutures. This suggested the</p> <p>16 coated sutures have higher pliability and thus</p> <p>17 facilitate better handling during surgical use.</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q You used the word "suggest." Why did</p> <p>21 you use that word?</p> <p>22 A Because personally I am not 100 percent</p> <p>23 convinced that the test used at Ethicon for</p> <p>24 stiffness is directly -- that the Ethicon</p> <p>25 definition of pliability and Ethicon definition of</p>	<p style="text-align: right;">196</p> <p>1 different samples produced not exactly the same</p> <p>2 result?</p> <p>3 BY MR. BONELLA:</p> <p>4 Q I'm asking you why No. 2 coated and</p> <p>5 No. 8 -- No. 6, uncoated, were closer together</p> <p>6 than the other ones?</p> <p>7 MR. TAMBURRO: Same objection.</p> <p>8 THE WITNESS: I have no explanations.</p> <p>9 It depends on how they were made and on the</p> <p>10 uniformity of the manufacturing processes and</p> <p>11 uniformity of their history, and no samples are</p> <p>12 always the same.</p> <p>13 This is why people do statistical</p> <p>14 analysis, and this is why we did our test and made</p> <p>15 our conclusions based on several samples, not just</p> <p>16 one sample of each group.</p> <p>17 BY MR. BONELLA:</p> <p>18 Q In your -- in the last -- in the bottom</p> <p>19 of that page under the Table 1 where you say this</p> <p>20 suggests that the coated sutures have higher</p> <p>21 pliability, then you say and thus facilitate</p> <p>22 better handling during surgical use.</p> <p>23 You don't have any experience to draw</p> <p>24 the conclusion that they facilitate better</p> <p>25 handling during surgical use, do you?</p>
<p style="text-align: right;">195</p> <p>1 stiffness are exactly the way somebody at ASTM</p> <p>2 would specify it.</p> <p>3 So I tried to be scientifically</p> <p>4 conservative, and I said that we found stiffnesses</p> <p>5 lower, and what is your understanding of</p> <p>6 pliability? If your understanding is the same as</p> <p>7 that of Rodeheaver and Ethicon, you will say that</p> <p>8 pliability is higher. If your understanding is</p> <p>9 different, you make your own conclusions.</p> <p>10 Q How did you pick the two curves that are</p> <p>11 shown on page 4 of your report, Exhibit 381, for</p> <p>12 the pliability tests?</p> <p>13 A They were more or less -- not</p> <p>14 mathematically, but visually typical for their</p> <p>15 groups.</p> <p>16 Q Sample 2 you had, for the coated suture,</p> <p>17 at 7.53.</p> <p>18 A Yes.</p> <p>19 Q And sample 6 of the uncoated was 8.00.</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Why were those two closer together than</p> <p>23 the other ones?</p> <p>24 MR. TAMBURRO: Objection, vague.</p> <p>25 THE WITNESS: You're asking me why</p>	<p style="text-align: right;">197</p> <p>1 A Yeah, I don't have any experience. It's</p> <p>2 from the literature, not from my opinion.</p> <p>3 Q Did you actually calculate the slopes</p> <p>4 yourself for the pliability test?</p> <p>5 A My engineers calculated.</p> <p>6 Q Did they actually calculate the</p> <p>7 pliability test data that's in the chart?</p> <p>8 A Yes.</p> <p>9 Q Did you check it?</p> <p>10 A I believe I did.</p> <p>11 Q You believe you did. Either no, you</p> <p>12 don't know, or you don't remember.</p> <p>13 MR. TAMBURRO: Objection, asked and</p> <p>14 answered.</p> <p>15 MR. BONELLA: You can't believe. Either</p> <p>16 you know you checked it, or, no, you didn't check</p> <p>17 it?</p> <p>18 MR. TAMBURRO: That's untrue. You can</p> <p>19 have a belief and not be 100 percent sure either</p> <p>20 way. He gave you his answer.</p> <p>21 THE WITNESS: Maybe it's a good</p> <p>22 definition. I don't remember 100 percent, but I</p> <p>23 am almost sure that I checked all the calculations</p> <p>24 in all the tests.</p> <p>25 BY MR. BONELLA:</p>

50 (Pages 194 to 197)

<p style="text-align: right;">198</p> <p>1 Q Can the slope of the -- when generating 2 the preload, when you were applying the preload, 3 can that be used to generate pliability test data? 4 A No, but preload is not increasing. 5 Preload is constant. 6 Q No, while you're applying the preload, 7 you're trying to get it to .5. 8 A During the increase of the load from 9 zero to whatever, half kilogram or what -- 10 Q Yes. 11 A -- it can be used, but the data would be 12 not repeatable because you're starting from the 13 not well defined level, from the poorly defined, 14 not well defined. This is the idea of preload, to 15 give you a well defined starting level. 16 Q I need to use the restroom. Let's take 17 a break. 18 THE VIDEOGRAPHER: Off the record at 19 2:18:15. 20 (A discussion was held off the record.) 21 THE VIDEOGRAPHER: On the record at 22 2:25:05. 23 BY MR. BONELLA: 24 Q Let's move on to the next set of tests 25 that you did, the knot slippage strength tests.</p>	<p style="text-align: right;">200</p> <p>1 pliability test data, Table 1, there's experiment 2 numbers 1 through 8. 3 A Yes. 4 Q Do the experiment numbers 1 through 8 5 correspond with -- 6 A Sample numbers. 7 Q -- the samples numbers in Exhibit 403 8 and Exhibit 393? 9 A Yes. 10 Q And can you tell me -- did I ask you 11 this? I'm not sure if I asked you. 12 Is Exhibit 403 the data for the 13 pliability test data for the uncoated sutures? 14 A Yes. 15 Q Next let's talk about the knot slippage 16 strength tests, the next test you did, right? 17 A Yes. 18 Q Okay. Now, this one you did a -- you 19 tied a square knot, right? 20 A Yes. 21 Q Okay. And the set-up is shown in 22 Figure 4 of your report? 23 A Pardon me? 24 Q The set-up is shown in Figure 4? 25 A Yes.</p>
<p style="text-align: right;">199</p> <p>1 Before we do that, in this Exhibit 382, 2 the four pages that represented -- there's a 3 Table 1, pliability test data, in that on page 4 CETR 77? 5 A Yes. 6 Q Is there any difference between that and 7 the Table 1 in your report, Exhibit 381, at 8 page 4? 9 A No, I'm sorry, the table is exactly the 10 same. The difference is only in the plots, as I 11 described them in the morning. 12 (DePuy Mitek Exhibit No. 403 was marked 13 for identification.) 14 BY MR. BONELLA: 15 Q I'm also going to show you DePuy Mitek 16 Exhibit 403. I believe this is the data for the 17 modulus -- or the data for the pliability test for 18 the uncoated samples; is that correct? 19 A Yes. 20 Q Do you see how the samples in 21 Exhibit 393 and Exhibit 403, there's samples 1 22 through 8 of the coated and uncoated? Do you see 23 that? 24 A Yes. 25 Q And then in your report, in the</p>	<p style="text-align: right;">201</p> <p>1 Q What module did you use for the upper 2 loading? 3 A The same as in the previous test for 4 pliability. We used only Z motion, only the 5 vertical motion of the upper specimen and no other 6 modules. 7 The lower end was attached to the 8 stationary table, and the upper end to the 9 vertically moving loading system. 10 Q Okay. And did you tie one square knot 11 in each sample when you tested it; is that right? 12 A Yes. 13 Q And you soaked them in a .9 percent 14 weight -- I'm sorry, you soaked the samples in a 15 .9 percent weight volume sodium chloride for one 16 minute? 17 A Yes. 18 Q Did you do anything to measure how much 19 sodium chloride was picked up by each sample? 20 A No, we did not. 21 Q Okay. You applied a preload of 1 newton 22 to the sample; is that correct? 23 A Yes. 24 Q And then you say the parallel rods were 25 then pulled apart with a constant velocity of</p>

<p style="text-align: right;">202</p> <p>1 1 millimeter per second?</p> <p>2 A That's correct.</p> <p>3 Q Was that how the test was done?</p> <p>4 A Yes.</p> <p>5 Q Sure?</p> <p>6 A Yes.</p> <p>7 Q Okay. When you say the rods are being</p> <p>8 pulled apart at a constant velocity, it's only the</p> <p>9 upper rod that's actually being pulled; is that</p> <p>10 correct?</p> <p>11 A Yes. As I described, the lower was</p> <p>12 stationary and the upper was moving.</p> <p>13 Q So the upper one is actually moving up</p> <p>14 at 1 millimeter per second?</p> <p>15 A Yes, at constant speed.</p> <p>16 Q Then you say the force was continuously</p> <p>17 monitored and recorded?</p> <p>18 A Yes.</p> <p>19 Q What force?</p> <p>20 A The vertical force applied to the knot.</p> <p>21 Q So if I understand, you put a preload of</p> <p>22 1 newton, and then you're moving the upper part --</p> <p>23 A I'm sorry, preload was up. You</p> <p>24 understand. Preload was not in compression, in</p> <p>25 tension.</p>	<p style="text-align: right;">204</p> <p>1 A If you look at force versus time, for as</p> <p>2 long as knot is intact, when you increase -- with</p> <p>3 increasing the time, you are continuously</p> <p>4 increasing the distance, and you are continuously</p> <p>5 increasing the force.</p> <p>6 As soon as you do not see any further</p> <p>7 increase in force, this increase in distance, it</p> <p>8 means that you got slippage. It slips. It does</p> <p>9 not -- for as long as it takes resistance, for as</p> <p>10 long as it is intact, force is increasing with</p> <p>11 distance. As soon as it starts slipping, force</p> <p>12 stops increasing various distance.</p> <p>13 Q So in other words, when the force starts</p> <p>14 going down is when the --</p> <p>15 A When force stops increasing.</p> <p>16 Q Stops increasing?</p> <p>17 A It doesn't have to go down. It can stay</p> <p>18 constant.</p> <p>19 Q Okay. And so that's the value you chose</p> <p>20 for non-slippage?</p> <p>21 A For the moment of slippage, yes. This</p> <p>22 is how it defines the moment of slippage.</p> <p>23 Q How did you do that -- this is a force</p> <p>24 versus time curve?</p> <p>25 A Yes.</p>
<p style="text-align: right;">203</p> <p>1 Q Tension, yes. And then you were pulling</p> <p>2 at a constant velocity of 1 millimeter per second</p> <p>3 to move the upper brass rod, if you will?</p> <p>4 A Yes.</p> <p>5 Q And you're measuring the forces</p> <p>6 generated?</p> <p>7 A Yes, what force was required to maintain</p> <p>8 the constant speed, because when you are moving it</p> <p>9 apart, pulling them apart, the loop -- the knot is</p> <p>10 resisting the movement, so you have to</p> <p>11 continuously increase the force until there the</p> <p>12 knot unties or breaks.</p> <p>13 Q And the force that you're monitoring, is</p> <p>14 that the same force that was measured with the</p> <p>15 preload? So, for example, was it 1 newton</p> <p>16 preload, and then it was going up from there?</p> <p>17 A Yes.</p> <p>18 Q You say the force when the knot starts</p> <p>19 slipping was noted as the knot slippage force. Do</p> <p>20 you see that?</p> <p>21 A Yes.</p> <p>22 Q What do you mean by that?</p> <p>23 A It's very easy to see on the Figure 5 on</p> <p>24 the next page, page 6.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">205</p> <p>1 Q Did you do it from the curve, or did you</p> <p>2 do it from the data?</p> <p>3 A We -- the beginning of slippage -- I'm</p> <p>4 sorry, what is the difference between doing from</p> <p>5 the curve and doing from the data?</p> <p>6 Q Well, the data has lots of data points.</p> <p>7 I don't know.</p> <p>8 Let me just ask you this. How did you</p> <p>9 determine the -- you have -- in Table 2 you</p> <p>10 present the knot strength as slippage for the</p> <p>11 coated and uncoated samples, right?</p> <p>12 A Yes.</p> <p>13 Q How did you arrive at those values?</p> <p>14 A We just discussed with you.</p> <p>15 Q Yeah, but how did you pick the point,</p> <p>16 the values?</p> <p>17 A I see. So we picked the points at the</p> <p>18 beginning of slippage when force stopped</p> <p>19 increasing with strength. Physically, the</p> <p>20 algorithm. We did not do it subjectively. We</p> <p>21 tried to do it objectively, and we let software do</p> <p>22 it.</p> <p>23 Q You let the software do it?</p> <p>24 A Yeah. And for software to do it, we set</p> <p>25 up an algorithm that if within 2 seconds force</p>

# **EXHIBIT 20**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.  
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.  
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

**DECLARATION OF DR. NORM GITIS**

1. My name is Dr. Norm Gitis and I am the founder and president of the Center for Tribology ("CETR"), a privately held testing laboratory located in Campbell, California.
2. Tribology is the study of friction between interacting surfaces.
3. CETR has conducted suture testing using its tribology testing equipment -- the same equipment used to test FiberWire sutures in this case -- for the leading suture manufacturers in the world, including Ethicon, DePuy Mitek's sister company.
4. I am the same Dr. Norm Gitis who prepared the "Comparative Suture Testing" report dated March 23, 2006 ("the Gitis report").
5. At the request of counsel for defendants, in late April 2006, CETR produced a computer disc containing the underlying raw data supporting the Gitis report. At the time, I believed that all of the raw data was accurate and supported the results in the Gitis report.



6. I was deposed on June 21, 2006. A large portion of my deposition was devoted to the subject matter of the Gitis report, including questions directed to the methodologies I used in conducting my tests as well as questions directed to the data points collected during my tests.

7. During my deposition, there were also many questions regarding apparent inconsistencies between the results reported in the Gitis report and the raw data contained on the disc produced by CETR.

8. During the suture testing I conducted, millions of data points were generated, all of which were automatically generated by computer-operated testing equipment.

9. When I testified at my deposition that I “checked most of the results,” I was describing the finite number of results included in the final Gitis report and not the accuracy of each of the millions of data points automatically collected by computer during my testing.

10. I was concerned about the apparent inconsistencies that surfaced during my deposition and when I returned to CETR, I initiated an investigation into the possible reasons for those inconsistencies.

11. During my initial investigation, I also reviewed my deposition transcript and the questions raised by counsel for DePuy Mitek regarding my test results and the raw data. I also discussed the apparent inconsistencies between the raw data and the Gitis report with Dr. Michael Faynberg – CETR’s Software Manager, and Michael Vinogradov – CETR’s Manager of Applications and Testing.

12. My discussions with Dr. Faynberg centered around what type of computer malfunction could have caused these apparent inconsistencies and my discussions with Mr. Vinogradov centered more around the apparent inconsistencies themselves as they related to the testing that was done.

13. At the time, we found inconsistencies with the friction testing data collected. The calculations for friction coefficient appeared to be correct for some samples and incorrect for others. My initial belief was that the only reasonable explanation for the intermittent miscalculations was a computer malfunction, possibly caused by a virus. As described below, this is still my belief.

14. Some other issues we found during my initial investigation also had to do with the pliability testing. The Gitis report states that a constant *loading* rate of 0.33kg/s was applied to the suture. This did not appear to match the raw data on the disc and was part of the reason we believed there was a problem with the raw data, possibly caused by a virus. Based upon my subsequent investigation, I have since learned that this issue has nothing to do with data corruption. Rather, from my discussions with Mr. Vinogradov, I learned that the pliability of the samples was tested was by applying a constant *extension* rate of 0.11mm/s. This constant extension rate is correctly reported by the underlying data. Accordingly, the Gitis report should be corrected to properly state how the samples were tested.

15. CETR, as most businesses, had experienced from time to time computer viruses that infiltrated its computer system. CETR experienced these viruses both before and after I conducted suture testing for defendants.

16. After forming my belief that the only reasonable explanation for the inconsistencies was a computer malfunction, possibly caused by a virus, I immediately informed counsel for defendants.

17. Counsel for defendants discussed the issues with me in order to try to understand the scope and nature of the problem and to see if the data could be reconstructed as “un-corrupted” and then reported.

18. Based on my initial observations, and the fact that at the time, I could not explain the inconsistencies, I informed counsel for defendants that it was my belief that the safest course of action was simply to redo the entirety of the tests.

19. In late July 2006, counsel for defendants contacted me to tell me that counsel for DePuy Mitek was seeking detailed information regarding the virus, including the identity of the virus by name, the identity of the specific machines infected, an explanation of precisely what data are corrupted and how it affected the Gitis report.

20. I was also informed that DePuy Mitek insisted that I provide all information in my possession and in CETR's possession regarding the virus, including any action taken to address the virus.

21. I agreed to conduct this more detailed investigation into the data corruption as was being requested by DePuy Mitek.

22. I had begun conducting the more detailed investigation into the data corruption when I was suddenly and unexpectedly called out of the country on a family-related emergency for approximately three weeks beginning on August 1, 2006.

23. I immediately notified counsel for defendants of my emergency and told them that I would be back at CETR in approximately three-weeks.

24. I returned to CETR on August 21, 2006, but I was called out of the office again for most of the remainder of the week due to the same family-related emergency.

25. During my limited time in the lab the week of August 21, 2006, I conducted additional research into the data corruption and we now believe that only certain portions of one file of the data related to the suture testing was corrupted. Specifically, some of the data related to the friction testing was corrupted. As explained above, I now do not believe that the data related to the pliability test was corrupted.



26. The way in which friction coefficient was calculated for some samples appears to correspond to the friction force whereas it does not appear to correspond to the friction force for other samples.

27. My staff and I spent many hours attempting to determine the exact cause of these anomalies. Since some of the calculations are correct and other are not, my staff and I do not believe it is likely that some sort of human error could have caused these intermittent miscalculations.

28. Rather, my staff and I can only deduce that the intermittent calculations were caused by some sort of computer malfunction, which may have been caused by a virus.

29. Since I was only able to devote limited time to the additional investigation last week, I will be continuing my investigation this week -- the week of August 28, 2006 -- while I am back at CETR.

30. At this time, the only portion of my testing that appears to require repeating is the friction coefficient testing.

31. I plan on redoing the friction coefficient testing the same way I did it in my first set of tests. I will not change my test methods and I will be using samples manufactured in the same way as the samples used in my previous tests. If subsequent investigation reveals that data of any other tests is corrupted, I will not change my test methods.

32. In addition, during my additional investigation, other issues in the Gitis report were uncovered that do not appear to have anything to do with corrupt data.

33. Other issues in the Gitis report include inconsistencies between the plot numbers in the raw data files and the data reported in the tables for the knot slippage, knot run-down and tissue drag testing. These inconsistencies, however, are unrelated to data corruption.

34. In addition, there appears to be a typographical error in the reporting of the suture diameter. It should read 0.56mm and not 0.65mm.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed on: 8/28/06

Norm Gitis

Dr. Norm Gitis

# **EXHIBIT 21**



**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	<b>LEAVE TO FILE GRANTED ON:</b>
	)	
<b>Pearsalls Ltd.</b>	)	
<b>a Private Limited Company</b>	)	<b>September 5, 2006</b>
<b>of the United Kingdom</b>	)	
	)	
<b>Defendants.</b>	)	
	)	

**Mitek's Reply In Support of its Motion To Preclude Arthrex, Inc. and Pearsalls, Ltd. From  
Supplementing Their Expert Reports And Depositions**

## Table of Contents

I.	Overview of Reply .....	1
II.	Arthrex Should Not Be Permitted To “Supplement” Dr. Gitis’ Report .....	2
A.	Experts Are Not Permitted to Supplement Merely Because They “Deem” There to Be An Inaccuracy of Incompletion.....	2
B.	Scheduling Orders Control, And An Expert Is Not Simply Permitted To Supplement Just Because It Is More Than 30 Days Before Trial.....	3
III.	Arthrex Has Not Satisfied Its Burden of Showing That Dr. Gitis’ Report Was Inaccurate or Incomplete In A Way That Permits Supplementation .....	3
A.	Arthrex Has Not Provided <i>Prima Facie</i> Evidence of An Inaccuracy or Incompleteness Entitling It To Redo Dr. Gitis’ Expert Report .....	3
1.	Dr. Gitis Should Not Be Permitted to Redo the Friction Tests on the Basis of Unsubstantiated Allegations of a Computer Virus .....	4
2.	Dr. Gitis Should Not Be Permitted to Make Other Substantive Changes to his Report by Characterizing them as Corrections of Typographical Errors .....	5
3.	Dr. Gitis Should Not Be Permitted to Make Substantive Changes to His Report With Respect to the Pliability Testing Methods.....	7
4.	Dr. Gitis Should Not Be Permitted to Make Unspecified, “Garden Variety” Changes to His Report .....	9
B.	Arthrex Has Not Established that the Information About Alleged Errors Was Unavailable to Dr. Gitis Earlier .....	9
C.	Arthrex Has Basically Admitted That It Delayed Raising These Issues, Without Any Reasonable Explanation.....	10
IV.	Mitek Would Be Severely Prejudiced By Arthrex’s Supplementation .....	10
V.	Dr. Mukherjee Should Not Be Permitted To Supplement His Report.....	11
VI.	If Arthrex Is Permitted to Supplement, It Should Bear Costs to Mitek Associated with Redoing Expert Discovery.....	12
VII.	Conclusion .....	12

## Table of Authorities

### Federal Cases

<i>Akeva L.L.C. v. Mizuno Corp.</i> , 212 F.R.D. 306 (M.D. N.C. 2002) .....	2
<i>DAG Enterprises, Inc. v. Exxon Mobil Corp.</i> , 226 F.R.D. 95 (D. D.C. 2005).....	2, 3, 9, 10
<i>Minebea Co., Ltd. v. Papst</i> , 231 F.R.D. 3 (D. D.C. 2005).....	3
<i>Schumacher v. Tyson Fresh Meats, Inc.</i> , No. CIV 02-1027, 2006 WL 47504 (D. S.D. Jan. 5. 2006) .....	2
<i>Sharpe v. U.S.</i> , 230 F.R.D. 452 (E.D. Va. 2005) .....	2, 3, 9, 10
<i>Tracinda Corp. v. Daimlerchrylser AG</i> , 362 F. Supp. 2d 487 (D. Del. 2005).....	2
<i>Wilson v. Sundstrand Corp.</i> , Nos. C 6944, 6946, 2003 WL 22012673 (N.D. Ill. Aug. 25, 2003) .....	2

### Federal Statutes

Fed. R. Civ. P. 26(e)(1).....	2
-------------------------------	---

## I. Overview of Reply

Under the scrutiny presented by Mitek's motion, Arthrex's initial plan to redo Dr. Gitis' expert report because errors were allegedly caused by an unspecified and unverified computer virus has now morphed into a plan to redo Dr. Gitis' expert report because some errors were allegedly caused by an unspecified and unverified computer virus, other *substantive* errors were allegedly typographical errors, and other *substantive* errors were just, well, unexplained errors. But this is high stakes litigation. The Court's scheduling order – setting expert discovery deadlines – has to be respected by the parties.

Arthrex has known from the outset of this litigation that it would be attempting to argue non-infringement on the basis of tests purporting to show that the coating on its sutures affect properties such as pliability and flexibility – the types of tests Dr. Gitis carried out – and its plan to now redo or recast large portions of his report, long after the close of expert discovery and with less than three months to trial, should not be permitted. Arthrex and Dr. Gitis should have taken more care in carrying out tests and preparing Dr. Gitis' expert report.

Upon close examination, Arthrex's stated reasons for redoing tests and changing Dr. Gitis' report at this late date are speculative (an unsubstantiated "belief" that a virus corrupted some data) or, in some instances, simply not credible (because contrary to Dr. Gitis' deposition testimony). The timing of Arthrex's notification of problems with the Gitis report and the record reflect that any problems with Dr. Gitis' report are due to inadequate preparation and lack of diligence, *not* any reasons that would justify supplementation at this late date and the substantial prejudice that such supplementation would cause Mitek.

## II. Arthrex Should Not Be Permitted To “Supplement” Dr. Gitis’ Report

### A. Experts Are Not Permitted to Supplement Merely Because They “Deem” There to Be An Inaccuracy of Incompletion

Arthrex alleges that FED. R. CIV. P. 26(e)(1) permits an expert to “supplement” his report at his whim by merely “deeming” his report or deposition inadequate or incomplete in any respect (Arthrex Op. Br. at 2, 9-11). But, as Mitek explained in its opening memorandum, supplementation is not permitted under Rule 26 based on an expert’s “inadequate or incomplete preparation.” *Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002); *Sharpe v. U.S.*, 230 F.R.D. 452, 462 (E.D. Va. 2005) (denying supplementation to remedy experts’ “incomplete or inadequate review”). Rule 26 only permits supplementation based on “‘information that was not available at the time’” of the report. *DAG Enterprises, Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 109 (D. D.C. 2005) (emphasis in original) (citation omitted).

Not surprisingly, Arthrex’s position -- that experts are simply permitted to supplement their reports because they could have done a better job -- has been rejected because such a standard “would essentially allow for unlimited bolstering.” *Akeva L.L.C.*, 212 F.R.D. at 310. Tellingly, Arthrex’s “expert deem” standard is not supported by any case citation (Arthrex Op. Br. at 2), Arthrex cites no case permitting it to supplement simply because Dr. Gitis could have done a better job<sup>1</sup>, and Arthrex ignores all but one case cited in Mitek’s opening memorandum.<sup>2</sup>

---

<sup>1</sup> Arthrex’s citations to three cases are no help to it here because the facts are completely different. *Wilson v. Sundstrand Corp.*, Nos. 99 C 6944, 6946, 2003 WL 22012673, at \*7-\*8 (N.D. Ill. Aug. 25, 2003) (Arthrex Ex. 12) (permitting supplementation where opponent was on notice of proposed supplement before expert deposition began, supplementation was based on documents that expert did not have but alerted opponent he would have before deposition began, supplementation was before expert deposition was completed and before rebuttal expert reports were due, and there was no unreasonable delay); *Schumacher v. Tyson Fresh Meats, Inc.*, No. CIV 02-1027, 2006 WL 47504, at \*6 (D. S.D. Jan. 5. 2006) (Arthrex Ex. 10) (permitting rebuttal report to be served two weeks before expert was deposed); *Tracinda Corp. v. Daimlerchrysler AG*, 362 F. Supp. 2d 487, 506-07 (D. Del. 2005) (Arthrex Ex. 11) (addressing issue of whether expert’s trial exhibits were admissible, not whether an expert was entitled to supplement).

**B. Scheduling Orders Control, And An Expert Is Not Simply Permitted To Supplement Just Because It Is More Than 30 Days Before Trial**

Arthrex erroneously argues that it should be permitted to supplement under Rule 26(a)(3) because it is more than thirty days before trial (Arthrex Op. Br. at 10). Where, as here, there is a Court Scheduling Order that sets forth the deadline for expert discovery, that order should control. *DAG Enterprises*, 226 F.R.D. at 110 (holding that Rule 26 is “no safe harbor” for lack of diligence and failure to show good cause to ignore the deadline for expert discovery in Court’s scheduling order); *Sharpe*, 230 F.R.D. at 453-54, 462 (denying motion to supplement more than 30 days before trial because expert discovery was closed per scheduling order). Permitting Arthrex to supplement at anytime more than thirty days before trial, as Arthrex suggests, would nullify the scheduling order, result in unlimited supplementation and depositions, and permit litigants to “hold back” until thirty days before trial.

**III. Arthrex Has Not Satisfied Its Burden of Showing That Dr. Gitis’ Report Was Inaccurate or Incomplete In A Way That Permits Supplementation**

**A. Arthrex Has Not Provided *Prima Facie* Evidence of An Inaccuracy or Incompleteness Entitling It To Redo Dr. Gitis’ Expert Report**

Abandoning its “virus”-affected-the-entire-report-approach, Arthrex’s new tactic is to seek to (i) redo friction tests based upon a mere unsubstantiated “belief” about a “virus;” (ii) make substantive changes by calling them “typographical errors;” (iii) make substantive wholesale change to Dr. Gitis’ pliability test without any basis for the change; and (iv) make

---

<sup>2</sup> Arthrex refers to only one case from Mitek’s Opening Memorandum and incorrectly characterizes it as supporting Arthrex’s position (Arthrex Op. Br. at 10-11). But Arthrex is wrong because the court in *Minebea Co., Ltd. v. Papst* recognized that Rule 26 “permits supplemental reports only for the *narrow purpose* of correcting inaccuracies or adding information that was *not available at the time of the initial report*,” and struck the “majority” of a supplemental expert report, and permitted only some small supplementation where there was no prejudice and the expert was updating damages calculations. 231 F.R.D. 3, 7-8, 11 (D. D.C. 2005) (emphasis supplied).



other, unidentified, so-called “garden variety” corrections to the report. But in no instance has Arthrex satisfied Rule 26’s requirement that it prove inaccuracy or incompleteness as a condition precedent to supplementation.

**1. Dr. Gitis Should Not Be Permitted to Redo the Friction Tests on the Basis of Unsubstantiated Allegations of a Computer Virus**

With respect to the alleged “virus,” “computer malfunction,” and “data corruption” excuses put forth by Arthrex to justify Dr. Gitis redoing his friction tests (Arthrex Op. Br. at 1, 6-7), Arthrex provides absolutely no evidence of any electronic problem that caused any inaccuracy or incompleteness in his report. After Dr. Gitis’ extensive “investigation,” the only evidence Arthrex can muster is Dr. Gitis’ unsubstantiated “*belief*”<sup>3</sup> that a “*computer malfunction, possibly caused by a virus*” caused problems in the “calculations for friction” (Arthrex Ex. 3 at ¶13) (emphasis supplied).<sup>4</sup> No documents evidencing this virus have been produced. Dr. Gitis provides no explanation of what the errors were, how the calculations were in error, or how the computer malfunction could have caused the errors, much less the information requested by Mitek when it was first notified of the alleged virus. Thus, Arthrex fails to show that the friction calculations were inaccurate or incomplete due to this alleged virus, and it should not be permitted to supplement based on such an unsubstantiated “belief,”

---

<sup>3</sup> Dr. Gitis’ conclusion that it must have been a virus because he cannot determine another explanation is so preposterous it is barely worth addressing (Arthrex Ex. 3 at ¶16). The obvious explanation is human error in conducting the tests. Further, Mitek’s experts did not, as Arthrex suggests (Arthrex Op. Br. at 5, n. 6), recognize that the data was corrupt, just that it did not make sense in light of Dr. Gitis’ report (Arthrex Ex. 6 at 271:160272:7; Arthrex Ex. 7 at 27:22-28:2).

<sup>4</sup> Arthrex cannot even keep its story straight. Dr. Gitis carefully worded his declaration, and Arthrex carefully worded most of its opposition to say that Dr. Gitis “believed” that there was a virus (Arthrex Ex. 3 at ¶13; Arthrex Op. Br. at 1, 8, and 13). But in one instance, Arthrex states that Dr. Gitis has “determined” that certain data collected during his suture testing was corrupt (Arthrex Op. Br. at 10). That statement is unsupported.

particularly where the original belief that the virus had allegedly affected other aspects of the report is now admittedly false.

**2. Dr. Gitis Should Not Be Permitted to Make Other Substantive Changes to his Report by Characterizing them as Corrections of Typographical Errors**

Having abandoned its position that a virus contaminated all portions of Dr. Gitis' report, Arthrex now has other excuses for problems in the report. Now, it claims that the suture diameter reported in Dr. Gitis' report -- 0.65 mm -- was a typographical error, and that it should be 0.56 mm (Arthrex Op. Br. at 9, n.7).<sup>5</sup> Significantly, Dr. Gitis submits no evidence establishing that this was in fact a typographical error. Rather, he merely states that "there *appears* to be a typographical error" (Arthrex Ex. 3 at ¶34) (emphasis supplied). This unsubstantiated statement does not satisfy Rule 26's condition precedent requirement of showing an inaccuracy or incompleteness.

Further, this typo excuse is not believable. If there had been a typographical error, Dr. Gitis would have recognized it to be so at his deposition. But, even after extensive questioning about the suture diameter, he did not do so:

- Q. Okay. And the diameter you say is .65 millimeters.
- A. Measured this by caliper.
- Q. Did you measure the diameters?
- A. Yes.
- Q. Of each sample?
- A. Yes.
- Q. Every sample?
- A. Not every sample, but we measured it at least 10, 12 times, yeah.
- Q. And you always got .65 millimeters?
- A. Pardon me?
- Q. And you always got .65 millimeters?
- A. Yes.
- Q. For each sample?

---

<sup>5</sup> Suture diameter affects Dr. Gitis' "pliability" results.

- A. Yes.
- Q. So the coated and uncoated, did you measure the diameter?
- A. Yes.
- Q. And they were the same?
- A. Yes.
- Q. No difference?
- A. No difference as measured with a caliper.
- Q. And you calculated an average diameter?
- A. This is what we planned to do, but we didn't have to do it because many measurements that we did produced the same result, .65.
- Q. Okay, if you go to -- one column says non-absorbable and synthetic absorbable sutures, and there's a number 2. Do you see that?
- A. Yes.
- Q. And it has diameter limits of .5000 to .599 for that. Do you see that?
- A. Yes.
- Q. And the diameter you used of .655 [sic 0.65] is above those diameter limits, right?
- A. Yes.

(Ex. 25 at 153:11-154:9; 165:1-4; and 172:23-173:7). Further, at his deposition, it was pointed out to Dr. Gitis that his diameter measurements differed from those made by Pearsalls, the suture manufacturer (*id.* at 169:14-173:16). Yet, he never raised any issue of a typographical error at his deposition (*id.*). Most significantly, no evidence has been presented to show that it *was* a typographical error. Dr. Gitis did not record the diameter measurements when he made them, (*id.* at 174:7-10), so he has no documents that would show that this was a typographical error. Dr Gitis' inexplicable failure to keep written records of the measurements as he was making them made it more difficult for Mitek to take meaningful discovery into his test methods and results; his failure to have records should not now provide him with cover for redoing a sloppy report.

This new typo excuse, being raised for the first time *over two months* after Dr. Gitis' deposition and *four months* after Dr. Brookstein first criticized Dr. Gitis' report, is too little, too late and provides no basis for re-doing Dr. Gitis' expert report.

**3. Dr. Gitis Should Not Be Permitted to Make Substantive Changes to His Report With Respect to the Pliability Testing Methods**

Arthrex's counsel now asserts that Arthrex's pliability test were not performed as reported in Dr. Gitis' report *or* as Dr. Gitis testified at his deposition. Arthrex intends to redo Dr. Gitis' report to state that his pliability tests were performed at a *constant extension rate* of 0.11 mm/sec, not at a *constant loading rate* of 0.33 kg/sec, as specified in his report and as he stated at his deposition (Arthrex Op. Br. at 8, n.7).<sup>6</sup>

There is a difference between the two types of tests (Mitek Op. Br. Ex. 6 at ¶¶12-17), and Arthrex offers no proof (other than Dr. Gitis' self-serving statements) that Dr. Gitis actually performed a constant extension rate test, much less a constant extension rate test at 0.11 mm/sec. Dr. Gitis' typo allegations are not credible in view of his prior testimony that he determined from his own research that the test should be carried out using a *constant loading rate*, that he instructed his employees to conduct the test at a *constant loading rate*, and that he, himself, observed the tests:

- Q. Were you present for at least some of the actual testing of the pliability samples for pliability?
- A. Yes, I was present in at least some of each and every test, each type of test.
- Q. And how is that controlled by the machine?
- A. It is the same servo-control as we

---

<sup>6</sup> Mitek does not dispute that Dr. Gitis' data show that his pliability tests were not all run at a constant rate of loading of 0.33 kg/sec. But that does not mean that Dr. Gitis used a constant extension rate test instead of a constant loading rate test.

- discussed before.
- Q. It's measuring the *force applied*?
- A. Yes.
- Q. And it's programmed into it to *increase it*?
- A. Yes.
- Q. Who actually wrote this report?
- A. I did.
- Q. You did? So you put the *0.33 kilogram per second uniform increase* in?
- A. Yes.
- Q. Where did you get that from?
- A. From my engineers. They gave me the number.
- Q. You got that from them?
- A. Yeah.
- Q. Did you program yourself, did you put into the machine the *rate at which the load should go up*?
- A. No, I did not.
- Q. Do you have any documents where you specified the parameters for the test that should be inputted into the machine?
- A. Yes. If it's not provided in the Excel files -- what documents do you mean?
- Q. Like, for example, if you wrote, either typed up or handwritten, said to your assistant, said, okay, the pliability tests, here is how I want you to run it, 50 centimeter gauge length, *uniform increase of load at this rate*, preload of this. Did you make some kind of document?
- A. No.
- Q. You just orally told him?
- A. Yes.
- Q. Okay. And do you know how you arrived at the *.33 kilogram per second*?
- A. It was from some -- again, from the same references. From one of the references cited.
- Q. Either the --
- A. Rodeheaver or --
- Q. Bizwada patent?
- A. Yeah.

(Ex. 25 at 84:16-20; 152:1-9; and 175:1-176:11, emphasis added).

Despite this clear testimony, Arthrex now belatedly alleges that the pliability test was conducted differently than as stated in Dr. Gitis' report and at his deposition. These new allegations are just not believable on this sparse record and in light of Dr. Gitis' contradictory testimony. Thus, Arthrex has not satisfied its burden of establishing an inaccuracy that it is entitled to correct. Further, even if the test was done completely different than Dr. Gitis reported and testified, Rule 26 does not permit supplementation for such inadequate preparation. *See* cases cited in Mitek's Opening Br. at 5, n.4, 6, n.5, and 9, n.7.

#### **4. Dr. Gitis Should Not Be Permitted to Make Unspecified, "Garden Variety" Changes to His Report**

Finally, Arthrex contends it will be making so-called "garden variety" changes to Dr. Gitis' report (Arthrex Op. Br. at 9, n.7) – as if there are allowable, recognized changes to expert reports --, but Arthrex does not identify these changes. As a condition precedent to supplementing, Arthrex was required to show an inaccuracy or inconsistency that could not have been corrected at the time of the report. As Arthrex has not even identified the alleged changes, it has failed its burden of meeting Rule 26's requirements.

#### **B. Arthrex Has Not Established that the Information About Alleged Errors Was Unavailable to Dr. Gitis Earlier**

As a condition precedent to supplementing, Arthrex was required to show that the proposed supplementation is based on "*information that was not available* at the time" of the report or during expert discovery. *DAG Enters.*, 226 F.R.D. at 109-110; *Sharpe*, 230 F.R.D. at 462 (denying supplementation in part because of "unjustifiable delay"). Arthrex has not done so.

With respect to the alleged virus, Arthrex does not allege that the information that would have led to its discovery was unavailable to Dr. Gitis when he prepared his report in March 2006 or during expert discovery. Also, Dr. Gitis provides no explanation for not having reviewed his underlying data and uncovering the alleged virus in preparing his report or, at least, before his



June deposition. Dr. Gitis had plenty of time between his March report and his June deposition to find and investigate this “virus.” Indeed, Dr. Gitis testified that he had checked the results in his report, which include the friction data, which he now alleges is incorrect (Arthrex Op. Br. at 6). Although Dr. Gitis alleges to have begun an investigation immediately after his deposition on June 21, 2006, he did not provide any results of this investigation until over a month after his deposition and as expert discovery was closing. Further, the results of his investigation – allegedly locating a virus that affected all his work – turned out, by his own admission, to be false.

**C. Arthrex Has Basically Admitted That It Delayed Raising These Issues, Without Any Reasonable Explanation**

Arthrex provides no excuse for not having raised these alleged virus-created, typographical, and other errors until, five months after Dr. Gitis’ report was prepared, well after expert discovery has closed, and over two months since Dr. Gitis’ deposition. Further, Arthrex has not shown why any of this information was not discovered after Dr. Brookstein’s April rebuttal report, particularly when, Dr. Brookstein questioned the suture diameters used by Dr. Gitis (Mitek Op. Br. Ex. 3 at ¶49).

**IV. Mitek Would Be Severely Prejudiced By Arthrex’s Supplementation**

Ignoring the case law, Arthrex claims that any prejudice to Mitek is irrelevant to the supplementation issue (Arthrex Op. Br. at 15). But Arthrex is wrong. Courts routinely consider the issue of prejudice because a party seeking supplementation of this nature is basically asking to reopen expert discovery and to burden its opponent. *DAG Enters.*, 226 F.R.D. at 110; *Sharpe*, 230 F.R.D. at 462 (declining motion to supplement because opponent should not be prejudiced with supplementation while it is competing discovery and prepare for trial in the confines of the Court’s scheduling order).

Arthrex tries to minimize the supplementation as merely affecting a few paragraphs of Dr. Brookstein's expert report (Arthrex Op. Br. at 16-17), but that is a gross mischaracterization. If Arthrex is permitted to supplement, Mitek will want to use computer forensic experts, virus experts, and the like to analyze Dr. Gitis' equipment in order to check the veracity of the virus allegations. The veracity of these allegations are directly relevant to Dr. Gitis' credibility, as well as the substance of his opinions, and Mitek would be entitled to such discovery.

Dr. Gitis' equipment is in California, so conducting this investigation will be costly and time consuming. Further, Mitek will have to analyze each of Dr. Gitis' new test results and opinions, depose Dr. Gitis, depose Pearsalls' witnesses about the construction of the new samples being tested, have Dr. Brookstein prepare another responsive report (Mitek might ask for a different report and analyses from Dr. Brookstein because his current work was requested based on Dr. Gitis' work being so flawed), and have Dr. Brookstein deposed again. Mitek should not be burdened with the expense of these efforts. Nor should Mitek's counsel be burdened with this work while it preparing for trial, now about two months away. In fact, it is not even clear that there is sufficient time for Mitek to fully conduct its investigation and prepare expert reports in the time allotted. Arthrex and Dr. Gitis should not be rewarded for their careless work by burdening Mitek with a whole new round of issues and discovery as it prepares for trial.

#### **V. Dr. Mukherjee Should Not Be Permitted To Supplement His Report**

In its opening brief, Mitek argued that Dr. Mukherjee should not be permitted to supplement his report or deposition. Arthrex did not oppose that issue and expressed no intent to supplement his work. Accordingly, Mitek's motion with respect to Dr. Mukherjee is unopposed and should be granted.

**VI. If Arthrex Is Permitted to Supplement, It Should Bear Costs to Mitek Associated with Redoing Expert Discovery**

For all of the reasons outlined above and in Mitek's Opening Brief, Arthrex should not be permitted to turn back time and redo Dr. Gitis' report, as if the last six months of expert discovery never took place. If it is permitted to do so, however, Mitek should not be made to pay for Arthrex's and Dr. Gitis' sloppy work. The trial date should not slip because of Arthrex's mistakes, and Mitek should not bear additional legal costs because of Arthrex's mistakes.

Thus, if Arthrex is permitted to supplement, Mitek requests that the Court order that Arthrex produce Dr. Gitis' supplemental expert report no later than September 15, produce Dr. Gitis, Pearsalls' witnesses, and Dr. Mukherjee (who relied on Dr. Gitis' work) for deposition in Mitek's counsel's offices at an early and mutually convenient date, and compensate Mitek for the fees and costs associated with re-taking their depositions and stemming from any permitted supplementation.

**VII. Conclusion**

For the reasons set forth above, Mitek requests that Arthrex not be permitted to supplement Dr. Gitis' expert report. Alternatively, if Arthrex is permitted to do so, Mitek requests relief, as outlined above, to minimize the prejudicial effects to Mitek.

Date: August 31, 2006

DEPUY MITEK, INC.,  
By its attorneys,

/s/ Erich M. Falke  
\_\_\_\_\_  
Dianne B. Elderkin  
Lynn A. Malinoski  
Michael J. Bonella  
Erich M. Falke  
WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
17th and Market Streets  
Philadelphia, PA 19103  
(215) 568-3100

Daniel J. Gleason (BBO #194900)  
Michelle Chassereau Jackson (BBO 654825)  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA. 02210-2604  
(617) 439-2000

### **CERTIFICATE OF SERVICE**

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

**Mitek's Reply In Support of its Motion To Preclude Arthrex, Inc. and Pearsalls, Ltd. From Supplementing Their Expert Reports And Depositions**

was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber  
Dickstein Shapiro  
1825 Eye Street, NW  
Washington, DC 2006  
[saberc@dicksteinshapiro.com](mailto:saberc@dicksteinshapiro.com)

Raymond P. Ausrotas  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109  
[rausrotas@toddweld.com](mailto:rausrotas@toddweld.com)

Dated: September 5, 2006

/s/ Erich M. Falke  
Erich M. Falke

IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS

-----x  
DEPUY MITEK INC., a :  
Massachusetts Corporation, :  
Plaintiff, :  
vs. : Civil Action No.  
ARTHREX, INC., a Delaware : 04-12457  
Corporation, and PEARSALLS :  
LIMITED, a Private Limited :  
Company of the United :  
Kingdom, :  
Defendants. :  
-----x

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by  
counsel for the Plaintiff, pursuant to notice,  
commencing at 8:15 a.m., at the law offices of  
Dickstein Shapiro Morin & Oshinsky LLP, 2101 L  
Street, Northwest, Washington, D.C., before  
Dawn A. Jaques, Certified Shorthand Reporter  
and Notary Public in and for the District of  
Columbia, when were present on behalf of the  
respective parties:



<p>82</p> <p>1 Q. Thank you. The testing that you did in 2 connection with this case in your reports, who 3 actually did the testing?</p> <p>4 A. I did it together with two engineers in 5 my lab.</p> <p>6 Q. Okay. And what engineers?</p> <p>7 A. Michael Vinogradov and Vishal Khosla.</p> <p>8 Q. Can you spell their names, please?</p> <p>9 A. Michael V-I-N-O-G-R-A-D-O-V, Vinogradov, 10 and Vishal K-H-O-S-L-A, Khosla. One is from 11 Russia, one is from India.</p> <p>12 Q. I'm going to guess Mr. Vinogradov is 13 from Russia?</p> <p>14 A. Good guess.</p> <p>15 Q. What did Mr. Vinogradov do with respect 16 to the test? What was his role?</p> <p>17 A. He helped to set up the testers and 18 modules, and he did some of the tests together 19 with me.</p> <p>20 Q. What tests did Mr. Vinogradov do?</p> <p>21 A. Most of the tests, or maybe all of the 22 tests we kind of did together.</p> <p>23 Q. So Mr. Vinogradov was involved in all 24 the tests?</p> <p>25 A. Yeah, and same thing with Mr. Khosla.</p>	<p>84</p> <p>1 running, most of these tests took less than a 2 minute, right, actual running time?</p> <p>3 A. Not really. Depends on what you call 4 the running. You have to set up the specimen, and 5 for some of them you have to make notes, so most 6 of them took several minutes. So, yeah, I was in 7 and out of the room during this test.</p> <p>8 Q. And what percentage of the test did you 9 actually see?</p> <p>10 A. Maybe between 25 and 50 percent.</p> <p>11 Q. Okay. Is there any of the tests that 12 you didn't actually witness the test being done of 13 the tests that were done? Let me ask a better 14 question.</p> <p>15 There's pliability tests that you've 16 described. Were you present for at least some of 17 the actual testing of the pliability samples for 18 pliability?</p> <p>19 A. Yes, I was present in at least some of 20 each and every test, each type of test.</p> <p>21 Q. Okay. So you weren't present the whole 22 time for this set-up and loading of each sample; 23 is that right?</p> <p>24 A. That's correct.</p> <p>25 Q. And from the tests that were done, data</p>
<p>83</p> <p>1 Q. How did their roles, Mr. Vinogradov and 2 Mr. Khosla's roles, differ?</p> <p>3 A. Vinogradov is a more senior member of 4 the team, and he was involved fully in all the 5 tests that we did for Ethicon and U.S. Surgical, 6 and he was the only one who remembered something 7 from those old tests.</p> <p>8 So Michael was more senior. He was 9 helping mostly in setting up the tests, and Vishal 10 was helping mostly in running the tests, and I was 11 like in and out. I was not there hundred percent 12 of the time.</p> <p>13 Q. Okay. You weren't there 100 percent of 14 the time for the set-ups; is that right?</p> <p>15 A. For all of it, for the set-ups and the 16 test. So they will do the set-up, I would come 17 approve or not approve, and then we would start 18 running tests. I would come out, come back and 19 see what is happening.</p> <p>20 Q. Did you approve each set-up after it was 21 done before the test was run?</p> <p>22 A. Yeah, of course.</p> <p>23 Q. You visually looked at each set-up?</p> <p>24 A. Yes.</p> <p>25 Q. And in terms of when the tests were</p>	<p>85</p> <p>1 was generated, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And all the data that was 4 generated, was that computer generated?</p> <p>5 A. Yes.</p> <p>6 Q. And then from the computer-generated 7 data, some calculations and results were 8 presented?</p> <p>9 A. Yes.</p> <p>10 Q. Who did the calculations?</p> <p>11 A. Two of them, Michael and Vishal.</p> <p>12 Q. Okay. What was your involvement in the 13 calculations?</p> <p>14 A. We discussed the formula used, and I 15 checked the results.</p> <p>16 Q. Did you check every result, or just kind 17 of spot check it?</p> <p>18 A. I checked most of the results.</p> <p>19 Q. Okay. Did you instruct Mr. Vinogradov 20 and Mr. Khosla as to how to -- as to what formulas 21 to use and how to generate the results from the 22 data?</p> <p>23 A. How to generate results, I don't have to 24 instruct them. They know how to do it.</p> <p>25 What formula to use, maybe it was not my</p>

<p>150</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And then the second, is Z a zero?</p> <p>4 A. Yes.</p> <p>5 Q. Does that tell you this is where the</p> <p>6 test started after the preload was applied?</p> <p>7 A. I'm sorry, I have to think much more how</p> <p>8 to read this raw data.</p> <p>9 Q. Have you read the raw data before today</p> <p>10 that was used for the test?</p> <p>11 A. In my life? For this testing? No.</p> <p>12 Q. No, okay.</p> <p>13 A. I was looking only at the results.</p> <p>14 Q. Okay. Do you see the force column?</p> <p>15 A. Yes.</p> <p>16 Q. And at the time, .504 -- the force being</p> <p>17 applied to the specimen is .55 kilograms, right?</p> <p>18 A. Yes.</p> <p>19 Q. In your paper, in your page 3 --</p> <p>20 A. Yes.</p> <p>21 Q. -- of your report, you say the suture</p> <p>22 was preloaded with a tension of .5 kilograms.</p> <p>23 Preloaded suture was then pulled at a force,</p> <p>24 uniformly increasing at a rate of .33 kilograms</p> <p>25 per second.</p>	<p>152</p> <p>1 Q. And how is that controlled by the</p> <p>2 machine?</p> <p>3 A. It is the same servo-control as we</p> <p>4 discussed before.</p> <p>5 Q. It's measuring the force applied?</p> <p>6 A. Yes.</p> <p>7 Q. And it's programmed into it to increase</p> <p>8 it?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So the column F sub Z, after the</p> <p>11 preload was applied, should that be going up at a</p> <p>12 rate of .33 kilograms per second?</p> <p>13 A. Yes.</p> <p>14 Q. What we're going to do is we have a CD</p> <p>15 with the data on it, if that's easier for you to</p> <p>16 look at.</p> <p>17 A. Yeah, it will be much easier.</p> <p>18 Q. It's Bates number ARM 25902. It's</p> <p>19 entitled CETR Raw Data.</p> <p>20 Do you have a later flight option?</p> <p>21 A. I thought we already finished.</p> <p>22 Q. Not quite.</p> <p>23 A. Go on with the rest of your questions.</p> <p>24 Q. Let me ask you while he's loading that</p> <p>25 up, I'll ask you a question. Page 3 at the top</p>
<p>151</p> <p>1 A. Yes.</p> <p>2 Q. Now, the uniform increase in rate you're</p> <p>3 talking about, is that uniform increase in the</p> <p>4 load that's applied to the specimen?</p> <p>5 A. Yes.</p> <p>6 Q. So you applied a .5 kilogram preload to</p> <p>7 specimen, right?</p> <p>8 A. Yes.</p> <p>9 Q. And then you increase that .5 kilogram</p> <p>10 preload at a rate of .33 kilograms per second</p> <p>11 uniformly, right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. So at time --</p> <p>14 A. Uniform in time, yeah.</p> <p>15 Q. So at, say when the actual -- after the</p> <p>16 preload is applied, if you call that time zero,</p> <p>17 after the first second, the load applied should be</p> <p>18 .5 --</p> <p>19 A. Plus .33.</p> <p>20 Q. Would be .83?</p> <p>21 A. Yes.</p> <p>22 Q. And then it goes up?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. And it goes up uniformly, so for each --</p> <p>25 A. Yes.</p>	<p>153</p> <p>1 you say the suture of 50 millimeters in length.</p> <p>2 A. Yes.</p> <p>3 Q. So you used a 50 millimeter gauge line</p> <p>4 for each sample?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. What device did you use to</p> <p>7 measure the gauge lines?</p> <p>8 A. Caliper.</p> <p>9 Q. Caliper?</p> <p>10 A. Yeah.</p> <p>11 Q. Okay. And the diameter you say is .65</p> <p>12 millimeters.</p> <p>13 A. Measured this by caliper.</p> <p>14 Q. Did you measure the diameters?</p> <p>15 A. Yes.</p> <p>16 Q. Of each sample?</p> <p>17 A. Yes.</p> <p>18 Q. Every sample?</p> <p>19 A. Not every sample, but we measured it at</p> <p>20 least 10, 12 times, yeah.</p> <p>21 Q. And you always got .65 millimeters?</p> <p>22 A. Pardon me?</p> <p>23 Q. And you always got .65 millimeters?</p> <p>24 A. Yes.</p> <p>25 Q. For each sample?</p>

<p style="text-align: right;">154</p> <p>1 A. Yes.</p> <p>2 Q. So the coated and uncoated, did you</p> <p>3 measure the diameter?</p> <p>4 A. Yes.</p> <p>5 Q. And they were the same?</p> <p>6 A. Yes.</p> <p>7 Q. No difference?</p> <p>8 A. No difference as measured with a</p> <p>9 caliper.</p> <p>10 Q. Okay. I'm going to show you -- here's</p> <p>11 the computer. I think that your data is in files,</p> <p>12 and there's one that says "Modulus Raw Plots." Do</p> <p>13 you see that? I believe that's your --</p> <p>14 A. Yeah.</p> <p>15 Q. If you could open up that file of the</p> <p>16 modulus raw plots file. I think that's what we're</p> <p>17 looking at here. Is this coated or uncoated, or</p> <p>18 is it both?</p> <p>19 A. No, it seems to be opening. Hopefully</p> <p>20 it will open.</p> <p>21 Q. That's the uncoated graph, right?</p> <p>22 A. Maybe I will reduce magnification.</p> <p>23 Yeah.</p> <p>24 Q. Can you find -- we were looking at the</p> <p>25 printouts of the coated. Can you find the coated</p>	<p style="text-align: right;">156</p> <p>1 explain for a second -- I'm sorry, did you ask me</p> <p>2 a question, why it's every time 10.04 or 10.05 or</p> <p>3 10.06?</p> <p>4 Q. No.</p> <p>5 A. Because of its servo-control, so it</p> <p>6 always measures the real time. It says go for 10</p> <p>7 seconds, but it measures with the accuracy of</p> <p>8 hundredths of a second, so every time it's 10.06,</p> <p>9 10.05, 10.04. Every time it's slightly different.</p> <p>10 Q. I'm just going to move it over.</p> <p>11 A. Yeah, sure, sure.</p> <p>12 Q. What's going on here?</p> <p>13 A. I don't know what Erich did to it.</p> <p>14 Q. Now we're all the way on the left-hand</p> <p>15 side. See it says radius minus 13.136, 10.05.</p> <p>16 Looks like that's in the third column, right?</p> <p>17 A. Yeah, perfect. This is what we see now,</p> <p>18 right?</p> <p>19 Q. I don't know that we're seeing all the</p> <p>20 digits in the spreadsheet. Is there more digits</p> <p>21 in there?</p> <p>22 A. Maybe if we increase the width of the</p> <p>23 column. Yeah, now we see.</p> <p>24 Q. So, for example, if this is Sample 2,</p> <p>25 the test is actually starting at line 4694.</p>
<p style="text-align: right;">155</p> <p>1 in that file?</p> <p>2 Okay, there's the graph for the coated,</p> <p>3 right? Okay. Now, if you go to the data for the</p> <p>4 coated that we were looking at on the printouts,</p> <p>5 there's the data, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And we're looking at here part</p> <p>8 way down. If you go all the way to the top, right</p> <p>9 there, that is the top, this is the setting of the</p> <p>10 preload, right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, could you go down and find</p> <p>13 where the preload stops and the test, if you will,</p> <p>14 if you want to call it that, the test part of it</p> <p>15 begins?</p> <p>16 A. Okay, one sec. I was there, and I just</p> <p>17 lost it. Erich, we need you, only your hands can</p> <p>18 work with this. I just saw it a second ago.</p> <p>19 Q. So that's where the actual --</p> <p>20 A. You'll see 10 seconds. 10 seconds were</p> <p>21 over, and preload was over. I'm looking at time.</p> <p>22 Q. Right. And -- okay. I see on the</p> <p>23 printout, see, for example, on column 2 it says</p> <p>24 No. 2, radius, velocity, duration?</p> <p>25 A. Because you know what, because I will</p>	<p style="text-align: right;">157</p> <p>1 A. Right.</p> <p>2 Q. Right, which would be this line here for</p> <p>3 Sample 2, see how it matches up 0.5, 13.629,</p> <p>4 30.3790. See that?</p> <p>5 A. Yeah.</p> <p>6 (DePuy Mitek Exhibit No. 396 was marked</p> <p>7 for identification.)</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. Okay. I'm going to mark 396 as this</p> <p>10 page where it looks like the preload had finished</p> <p>11 and the testing is starting for at least</p> <p>12 Samples 1, 2 and 3. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So let's just look at Sample 2.</p> <p>15 Sample 2 at time zero, right --</p> <p>16 A. Yes.</p> <p>17 Q. -- the load is .5?</p> <p>18 A. Yes.</p> <p>19 Q. And time zero is measured in seconds,</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And you said the load is going up .33</p> <p>23 uniformly per second?</p> <p>24 A. Yes.</p> <p>25 Q. So at time T equals 1, the load should</p>

<p style="text-align: right;">162</p> <p>1 A. Yes.</p> <p>2 Q. Is there an assumption in the test that</p> <p>3 it's a uniform increase in --</p> <p>4 A. Yes.</p> <p>5 Q. And that assumption is wrong?</p> <p>6 A. No, I didn't say so.</p> <p>7 Q. I didn't say you did. I said if the</p> <p>8 assumption is wrong, how does that -- what does</p> <p>9 that do to the results?</p> <p>10 A. It would have no result -- no effect on</p> <p>11 the results.</p> <p>12 Q. Even if it wasn't uniform?</p> <p>13 A. Yes.</p> <p>14 Q. Why is that?</p> <p>15 A. Because we loaded sutures uniformly or</p> <p>16 not, whether we loaded with -- at the rate of .3</p> <p>17 kilogram per second or .03 kilogram per second, we</p> <p>18 saw clear differences between coated and uncoated,</p> <p>19 clear repeatable statistically different results</p> <p>20 for coated and uncoated sutures.</p> <p>21 Q. If you didn't load them uniformly,</p> <p>22 right, each one was loaded at a different rate --</p> <p>23 A. Yes.</p> <p>24 Q. -- you would generate different strains</p> <p>25 per time, right?</p>	<p style="text-align: right;">164</p> <p>1 Q. Yeah. You assumed that the diameter was</p> <p>2 constant along those lengths?</p> <p>3 A. No, we didn't make this assumption.</p> <p>4 Q. You didn't?</p> <p>5 A. No.</p> <p>6 Q. Well, you used -- did you use 0.65</p> <p>7 millimeters in calculating all the stiffness data</p> <p>8 that's presented in Table 2?</p> <p>9 A. Yes.</p> <p>10 Q. So did you actually measure along every</p> <p>11 point of the length of every suture?</p> <p>12 A. No.</p> <p>13 Q. Okay. So you did some measurements?</p> <p>14 A. We assumed that this data is the average</p> <p>15 diameter, but we did not assume -- we did not make</p> <p>16 any assumptions on each cylinder being ideally --</p> <p>17 ideally cylindrical because nothing is ideal in</p> <p>18 this life.</p> <p>19 If you want to characterize cross</p> <p>20 section of the cylinder, you have to deal with</p> <p>21 average parameters for the cylinder.</p> <p>22 Q. Well, doesn't the test assume that</p> <p>23 applying a -- you measured diameters along the</p> <p>24 length of some specimens for the pliability tests?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">163</p> <p>1 A. Yes.</p> <p>2 Q. So the graphs that generated would not</p> <p>3 be correct?</p> <p>4 A. No, the graphs would still stay because</p> <p>5 this graph is just one column versus another</p> <p>6 column. You have column -- we just looked with</p> <p>7 you at the computer. You have column force, and</p> <p>8 you have column strain, and you just plot force</p> <p>9 versus strain or strain versus force, and whether</p> <p>10 it was increasing uniformly or not, it cannot</p> <p>11 change this graph.</p> <p>12 Q. Let me ask you a different question. If</p> <p>13 the loads didn't increase at a uniform rate, at</p> <p>14 the same uniform rate on each sample, you can't</p> <p>15 really compare the graphs to each other?</p> <p>16 A. If for every sample the rates were</p> <p>17 different, it would jeopardize the results.</p> <p>18 Q. Okay. You assumed in this test that the</p> <p>19 diameter was constant along the length of each</p> <p>20 specimen, right?</p> <p>21 A. I didn't understand your question.</p> <p>22 Q. Each specimen, for the pliability test,</p> <p>23 you assumed that the diameter --</p> <p>24 A. We recall specimens at 50 millimeter</p> <p>25 from the suture.</p>	<p style="text-align: right;">165</p> <p>1 Q. And you calculated an average diameter?</p> <p>2 A. This is what we planned to do, but we</p> <p>3 didn't have to do it because many measurements</p> <p>4 that we did produced the same result, .65.</p> <p>5 Q. Who measured the diameter?</p> <p>6 A. Michael Vinogradov.</p> <p>7 Q. How much experience does he have in</p> <p>8 measuring suture diameters?</p> <p>9 A. In measuring suture diameters, his</p> <p>10 experience is very, very limited, but in measuring</p> <p>11 diameters of cylinders, he has plenty of</p> <p>12 experience.</p> <p>13 Q. How about in measuring diameter of</p> <p>14 specimens on the order of the size of a suture?</p> <p>15 A. We have lots of experience for this.</p> <p>16 Q. No, him personally.</p> <p>17 A. Him personally.</p> <p>18 Q. Does the device that you used to measure</p> <p>19 diameter, specifically what was the device used?</p> <p>20 A. Caliper.</p> <p>21 Q. What's the type and name of the caliper?</p> <p>22 A. Made by a Japanese company called</p> <p>23 Mitutoyo, but I don't remember the particular</p> <p>24 model.</p> <p>25 Q. Was it digital or --</p>

166

1 A. Yeah, digital, sure.

2 Q. Okay. How many decimal places does it

3 read out in?

4 A. I do not remember.

5 Q. Okay. Do you know what its accuracy or

6 sensitivity is?

7 A. I do not remember.

8 Q. Do you know if it's designed to measure

9 specimens on the order of sutures? I'm sorry, do

10 you know if the caliper that was used is

11 specifically designed to measure suture diameters?

12 A. I know that it was not designed

13 specifically for sutures. It's just a general

14 engineering caliper that we use in our lab. We

15 have several of them. We ordered them together,

16 they are from the same bunch, Mitutoyo calipers,

17 but I don't believe that Mitutoyo targets suture

18 market with those calipers.

19 Q. Okay. Doesn't the test -- the tests

20 that you're doing -- well, are you saying that

21 you -- did you verify that the specimens that were

22 tested in the pliability tests were actually

23 circular in diameter?

24 MR. TAMBURO: Objection, vague.

25 THE WITNESS: No, we did not.

167

1 BY MR. BONELLA:

2 Q. Okay. So there was an assumption that

3 they were circular in diameter?

4 A. They looked circular.

5 Q. Okay, but they're very small?

6 A. Yes.

7 Q. Okay. And it was also assumed that

8 they're circular in diameter along the entire

9 length of the specimen, the 50 millimeters that

10 was tested in pliability tests?

11 A. We did not need this assumption. If you

12 are talking about our calculations of the moment

13 of inertia where we used diameter of the cylinder,

14 yes, it was assumed that average diameter was .65,

15 but we did not need to go and to measure each and

16 every cross section over the length of

17 50 millimeters, because in practical engineering,

18 you just need to have the average diameter for

19 your calculations of the moment of inertia.

20 Q. Okay. How many measurements did you

21 take of diameter?

22 A. I believe I already answered. We did

23 minimum 10, 12 on the coated, and minimum 10, 12

24 on the uncoated.

25 One of the -- why we did it separately

168

1 on coated and uncoated, because in the beginning

2 we were not sure whether coating would introduce

3 some thickness, so we did it very carefully.

4 MR. TAMBURO: Do you want to break for

5 lunch soon?

6 MR. BONELLA: Yeah. Let's just finish

7 this up.

8 THE WITNESS: It's about end. Let's

9 finish.

10 (DePuy Mitek Exhibit Nos. 399 and 400

11 were marked for identification.)

12 BY MR. BONELLA:

13 Q. I'm going to show you DePuy Mitek

14 Exhibit 399 and DePuy Mitek Exhibit 400. I ask

15 you if you've ever seen these documents before?

16 A. I don't remember ever seeing these

17 documents.

18 Q. Okay. Do you see where -- they're from

19 Pearsalls?

20 A. Yes.

21 Q. And they're dated February 17th, 2006.

22 Do you see that?

23 A. Where shall we see the date?

24 Q. Down the bottom on the left-hand side.

25 A. Oh, yes.

169

1 Q. And do you see on Exhibit 399, do you

2 see it says -- underneath here it says coated with

3 Nusil Med2174 Silicone?

4 A. Yes.

5 Q. And if you look at Exhibit 400, in the

6 product line, third line of the document, it says

7 Blue Fibre Wire Uncoated. Do you see that?

8 A. Yes.

9 Q. You don't know if these documents

10 pertain to the samples that you tested, do you?

11 A. I don't know.

12 Q. They weren't provided to you?

13 A. They have not been provided.

14 Q. If you look at Exhibit 399 and look

15 under the diameter column or row, there's an

16 average/mid/max?

17 A. Yes.

18 Q. And the average diameter was .586,

19 minimum was .570, and the max was .599.

20 Do you see that?

21 A. Yes.

22 Q. This is for a coated sample. It's

23 different than what you assumed -- or you used,

24 I'm sorry, .65?

25 A. Yes.



<p style="text-align: right;">170</p> <p>1 Q. Okay. Can you explain why there would 2 be a difference if this applies to the same 3 suture?</p> <p>4 MR. TAMBURIO: Objection, calls for 5 speculation.</p> <p>6 THE WITNESS: I cannot explain. I don't 7 know --</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. And you agree that the .65 that you used 10 is above the maximum that was measured at least 11 for this sample in Exhibit 399?</p> <p>12 A. Yes.</p> <p>13 Q. If you look at Exhibit 400, for the 14 uncoated the diameter average was .600 15 millimeters, the min was .570, and the max was 16 .635. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And so for this uncoated sample in 19 Exhibit 400, the maximum diameter that was 20 measured is less than the diameter that you used, 21 right?</p> <p>22 A. Yes.</p> <p>23 Q. Can you explain that?</p> <p>24 A. No, I cannot.</p> <p>25 Q. And do you see how the uncoated in</p>	<p style="text-align: right;">172</p> <p>1 the deposition of Dr. Mukherjee or from some 2 rebuttal or report of Dr. -- of your expert 3 witness.</p> <p>4 Q. I'll show you the next exhibit.</p> <p>5 THE VIDEOGRAPHER: I need to change. It 6 takes 20 seconds.</p> <p>7 MR. BONELLA: That's all right, keep 8 going.</p> <p>9 (DePuy Mitek Exhibit No. 401 was marked 10 for identification.)</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. DePuy Mitek Exhibit 401 -- I'm sorry, I 13 labeled the inside page, but it's a 4-page 14 document. Part of it is not from the same 15 document, but the last page is suture size and 16 diameter chart. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 MR. TAMBURIO: I'm sorry, are you 19 representing this as a USP chart?</p> <p>20 MR. BONELLA: The last page is.</p> <p>21 MR. TAMBURIO: The last page is.</p> <p>22 BY MR. BONELLA:</p> <p>23 Q. Okay, if you go to -- one column says 24 non-absorbable and synthetic absorbable sutures, 25 and there's a number 2. Do you see that?</p>
<p style="text-align: right;">171</p> <p>1 Exhibit 400 and the coated in 399 had different 2 measurements for average/minimum/maximum 3 diameters?</p> <p>4 A. Yes -- no. I see the same minimums, but 5 different averages and maximums.</p> <p>6 Q. Yes, I'm sorry, thank you. But didn't 7 find any difference in the diameters when you 8 measured them?</p> <p>9 MR. TAMBURIO: Objection, 10 mischaracterizes testimony.</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. I'm sorry, did you find differences in 13 diameters between the coated and uncoated samples 14 that you tested in the pliability tests?</p> <p>15 A. We specifically looked for it, and we 16 didn't find the differences.</p> <p>17 Q. Okay. Now, are you familiar with the 18 USP sizing for diameters?</p> <p>19 A. No, I am not.</p> <p>20 Q. Okay. Are you familiar with a No. 2 21 designation for suture?</p> <p>22 A. No.</p> <p>23 Q. Did you ever hear of a diameter range 24 for a No. 2 suture?</p> <p>25 A. No. Maybe I heard about it either from</p>	<p style="text-align: right;">173</p> <p>1 A. Yes.</p> <p>2 Q. And it has diameter limits of .5000 to 3 .599 for that. Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And the diameter you used of .655 is 6 above those diameter limits, right?</p> <p>7 A. Yes.</p> <p>8 Q. Did you test any sutures other than 9 No. 2 size suture?</p> <p>10 A. I did not test any sutures rather than 11 those spools I received from the law firm.</p> <p>12 Q. If the diameter of the coated and 13 uncoated were different, that would change the 14 pliability test data stiffness that's presented in 15 table -- on page 4 of your report, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay, you want to break for lunch?</p> <p>18 MR. TAMBURIO: Sure.</p> <p>19 THE VIDEOGRAPHER: This is the end of 20 Tape 2, beginning of Tape 3. Off the record at 21 12:45:46.</p> <p>22 (Lunch break taken.)</p> <p>23 THE VIDEOGRAPHER: This is the beginning 24 of Tape 3 in the deposition of Dr. Norm V. Gitis. 25 On the record -- excuse me, can we go off the</p>



<p>174</p> <p>1 record? Off the record at 1:43:13.  2 (Pause in the proceedings.)  3 THE VIDEOGRAPHER: This is Tape 3 in the  4 deposition of Dr. Norm V. Gitis. On the record at  5 1:44:58.  6 BY MR. BONELLA:  7 Q. Were there any recordation of the  8 diameter measurements that you said were made? Is  9 there anywhere that was recorded?  10 A. No, it was not.  11 Q. According to the data, it shows for the  12 pliability tests that you had eight samples of  13 coated and uncoated that were reported in tests?  14 A. Yes.  15 Q. Okay. Other than the eight, did you do  16 any other samples that aren't recorded there?  17 A. No.  18 Q. Why did you choose eight?  19 A. Because among the references we cited,  20 some people tested five, some seven, some ten, so  21 we saw eight as somewhere in the middle.  22 Q. Okay. Any other reason?  23 A. Huh?  24 Q. Any other reason?  25 A. That's about it.</p>	<p>176</p> <p>1 A. No.  2 Q. You just orally told him?  3 A. Yes.  4 Q. Okay. And do you know how you arrived  5 at the .33 kilogram per second?  6 A. It was from some -- again, from the same  7 references. From one of the references cited.  8 Q. Either the --  9 A. 'Rodeheaver or --  10 Q. Bizwada patent?  11 A. Yeah.  12 Q. So this pliability test is actually --  13 the test you did is actually a tension test, isn't  14 it?  15 A. It's a pliability test.  16 Q. It's also a tension test, right?  17 A. Yes.  18 Q. And in order for it to be a pliability  19 test, certain assumptions have to be true, right?  20 A. Yes.  21 Q. Is one of the assumptions that the  22 compressive and tensile modulus of the specimen --  23 let me rephrase that.  24 Is one of the assumptions that the  25 compressive and tensile moduli are the same for</p>
<p>175</p> <p>1 Q. Who actually wrote this report?  2 A. I did.  3 Q. You did? So you put the 0.33 kilogram  4 per second uniform increase in?  5 A. Yes.  6 Q. Where did you get that from?  7 A. From my engineers. They gave me the  8 number.  9 Q. You got that from them?  10 A. Yeah.  11 Q. Did you program yourself, did you put  12 into the machine the rate at which the load should  13 go up?  14 A. No, I did not.  15 Q. Do you have any documents where you  16 specified the parameters for the test that should  17 be inputted into the machine?  18 A. Yes. If it's not provided in the Excel  19 files -- what documents do you mean?  20 Q. Like, for example, if you wrote, either  21 typed up or handwritten, said to your assistant,  22 said, okay, the pliability tests, here is how I  23 want you to run it, 50 centimeter gauge length,  24 uniform increase of load at this rate, preload of  25 this. Did you make some kind of document?</p>	<p>177</p> <p>1 the specimen?  2 A. It was not specifically the assumption  3 for this test.  4 Q. You didn't assume that one way or the  5 other?  6 A. No, we did not.  7 Q. You didn't consider it?  8 A. Again, as we discussed before lunch, we  9 just decided to use the same test as our  10 customers.  11 Q. So you didn't use -- you didn't consider  12 whether that was an assumption that goes into  13 applying this test for stiffness then?  14 MR. TAMBURRO: Objection, vague.  15 THE WITNESS: No, we did not spend much  16 time on considering assumptions of our customers.  17 BY MR. BONELLA:  18 Q. If the compressive and tensile moduli  19 for the FiberWire specimens you tested are not the  20 same, how would it affect the pliability test  21 results that you've prepared?  22 A. It's hard to say. Depends on their  23 levels.  24 Q. If they're different, if the compressive  25 and tensile moduli for the FiberWire samples are</p>

# **EXHIBIT 22**

LEXSEE 2006 US DIST LEXIS 28263

**SAINT-GOBAIN CORPORATION, Plaintiff/Counterclaim defendant, v  
GEMTRON CORPORATION, Defendant/Counterclaim plaintiff.**

**Case No. 1:04-cv-387**

**UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF  
MICHIGAN, SOUTHERN DIVISION**

*2006 U.S. Dist. LEXIS 28263*

**May 9, 2006, Decided**

**SUBSEQUENT HISTORY:** Motion granted by *Saint-Gobain Corp. v. Gemtron Corp.*, 2006 U.S. Dist. LEXIS 28268 (W.D. Mich., May 9, 2006)

**PRIOR HISTORY:** *St.-Gobain Corp. v. Gemtron Corp.*, 2006 U.S. Dist. LEXIS 27864 (W.D. Mich., May 9, 2006)

**COUNSEL:** [\*1] For Saint-Gobain Corporation, plaintiff: Barry J. Herman, Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Michael E. McCabe, Jr., Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

For Gemtron Corporation, defendant: Randall G. Litton, Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI; Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL.

For Facilitative Mediator, mediator: William W. Jack, Jr., Smith Haughey Rice & Roegge, PC, Grand Rapids, MI.

For Gemtron Corporation, counter-claimant: Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL; Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI.

For Saint-Gobain Corporation, counter-defendant: Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

**JUDGES:** Wendell A. Miles, Senior U.S. District Judge.

**OPINIONBY:** Wendell A. Miles

**OPINION:**

ORDER ON [\*2] SAINT-GOBAIN'S MOTION TO STRIKE THE APRIL 10, 2006 TAYLOR SUPPLEMENTAL EXPERT REPORT

Presently before the court is Plaintiff/Counterclaim defendant Saint-Gobain's Motion to Strike the April 10, 2006 Taylor Supplemental Expert Report (docket no. 270). Defendant/counterclaim plaintiff Gemtron has opposed the motion. For the reasons to follow, the court **GRANTS** the motion.

**Discussion**

Paul Taylor is Gemtron's damages expert. Saint-Gobain seeks to have Mr. Taylor's most recent "supplemental" expert report (titled "Second Supplemental Expert Report of Paul H. Taylor, April 10, 2006") excluded because the report was not provided at least 90 days before trial as required by *Fed.R.Civ.P. 26(a)(2)(C)*. Saint-Gobain also argues that Mr. Taylor's most recent report contains substantially increased figures for both lost profits and reasonable royalties and that Gemtron has not offered a justifiable excuse for submitting a new report so close to the trial date.

*Fed.R.Civ.P. 26(a)(2)(C)* requires expert reports to be disclosed "at least 90 days before the trial date or the date the case is to be ready for trial" "[i]n the absence of other directions from the court or stipulation [\*3] by the parties[.]" *Fed.R.Civ.P. 37(c)(1)* provides that

A party that without substantial justification fails to disclose information required by *Rule 26(a)* or *26(e)(1)*, or to amend a prior response to discovery as required by *Rule 26(e)(2)*, is not, unless such failure is

harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions. . . .

Gemtron does not dispute that it did not provide Mr. Taylor's most recent report at least 90 days before trial. However, Gemtron argues that there were reasons for the belated disclosure, namely that Mr. Taylor had requested more information, Saint-Gobain also wanted this documenting information, and the parties had agreed that Saint-Gobain could depose Mr. Taylor as well as present its own rebuttal expert. (Apparently, Saint-Gobain has decided not to call the rebuttal expert, Rodney Crawford, who is not listed in the final pretrial order.)

The issue could be viewed as simply one of supplementation of expert disclosures as [\*4] contemplated in *Fed.R.Civ.P. 26(e)(1)*, which in turn incorporates *Rule 26(a)(3)*, which requires disclosure at least 30 days before trial unless otherwise directed by the court. However, the court is not persuaded that Mr. Taylor's most recent report falls within boundaries of supplementation provided by *Rule 26(e)(1)*. Review of Mr. Taylor's earlier report, dated December 22, 2005, indicates that he reached a specific conclusion regarding Gemtron's lost profits which did not include lost unit sales of tempered glass because he had requested additional financial information from Gemtron which not yet been provided by the company for reasons having nothing to do with Saint-Gobain. Therefore, if his analysis was incomplete, it was incomplete because Gemtron did not provide its own expert with enough of its own financial information and not because of a lack of information from Saint-Gobain.

In addition, regarding reasonable royalty damages, Mr. Taylor's earlier report stated that he had "concluded to rely on the RoyaltySource and Licensing Economics Review data indicating industry and guideline patent(s) median royalty rates of approximately 5.0% of sales." Mr. Taylor does not in [\*5] that earlier report state in any way that his analysis of a reasonable royalty was incomplete. To allow Gemtron to seek a change in its expert's conclusions based solely on information, such as licensing agreements, pursued by Saint-Gobain would defeat the purpose of disclosure because it would permit the bolstering of a report based solely on a desire to answer the opposing party's anticipated challenges. This would effectively amount to unlimited expert opinion preparation. See *Akeva LLC v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D.N.C.2002) ("The Court cannot accept a definition of supplementation which would essentially allow for unlimited bolstering of expert opinions. *Rule 26(e)* envisions supplementation when a party's discov-

ery disclosures happen to be defective in some way so that the disclosure was incorrect or incomplete and, therefore, misleading. . . . It does not cover failures of omission because the expert did an inadequate or incomplete preparation. . . . To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would reek havoc in docket control and amount to unlimited expert opinion preparation"); [\*6] see also *Sharpe v. United States*, 230 F.R.D. 452, 462-463 (E.D. Va. 2005) (plaintiff not permitted to supplement expert reports in order to remedy incomplete review performed by experts). The obligation to supplement does not grant a party a right to ignore court deadlines, reopen discovery, find "new facts," generate new expert reports, and then claim different damages. *DAG Ent., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 110 (D.D.C. 2005).

Gemtron argues that Saint-Gobain is not prejudiced by the belated "supplementation" of Mr. Taylor's report. However, as noted above, Mr. Taylor's most recent report substantially increases his earlier damage calculations. These increased figures establish that Saint-Gobain is indeed prejudiced by the belated disclosure.

Finally, as for Gemtron's argument that the parties had an agreement regarding expert discovery, Gemtron has not shown that the parties had an agreement that Gemtron could supplement its expert report after December 22, 2005. The evidence provided by Gemtron suggesting an agreement between the parties indicates that counsel for Saint-Gobain anticipated that Mr. Taylor would be deposed "after supplemental [\*7] damages reports are exchanged." However, the e-mail documenting this agreement is dated November 1, 2005, several weeks before the date of Mr. Taylor's December 22, 2005 supplemental report; the e-mail does not imply that Saint-Gobain was agreeing to yet further supplementation after December, 2005. In addition, although Gemtron has submitted the affidavit of its counsel who states that Saint-Gobain's counsel said the parties "previously had agreed that Saint-Gobain's damages expert, Rodney L. Crawford, would be allowed to submit an expert report two weeks after [Taylor] was to be deposed[,]" this does not indicate an agreement on Saint-Gobain's part that it would not oppose amendment of Mr. Taylor's report. Gemtron has therefore not shown that Saint-Gobain agreed to a waive the 90-day disclosure requirement.

### Conclusion

For the foregoing reasons, the court GRANTS Saint-Gobain's motion. The April 10, 2006 Second Supplemental Expert Report of Paul Taylor is stricken and shall not be used as evidence at trial. n1

2006 U.S. Dist. LEXIS 28263, \*

n1 By way of a footnote in its response brief, Gemtron argues that "Mr. Taylor's report *will need to be supplemented at least one more time* to account for damages arising from the new shelves [recently added to the claims of infringement]" (emphasis supplied). It is noted that Gemtron has not requested permission to supplement Mr. Taylor's report yet again, and the current ruling is by no means intended to suggest that the court

would permit one or more additional amendments to the report of Gemtron's damages expert.

[\*8]

So ordered this 9th day of May, 2006.

Wendell A. Miles

Senior U.S. District Judge

# **EXHIBIT 23**



THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC.,  
a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC.,  
a Delaware Corporation and

PEARSALLS LTD.  
a Private Limited Company of  
the United Kingdom

Defendants.

Civil No. 04-12457 PBS

**DePuy Mitek, Inc.’s Motion to Preclude Arthrex, Inc. and Pearsalls Ltd. From  
“Supplementing” Their Expert Reports and Depositions**

Plaintiff DePuy Mitek, Inc. (“Mitek”) move to preclude Defendants Arthrex, Inc. and Pearsalls Ltd. (collectively, “Arthrex”) from “supplementing” their expert reports and depositions under FED.R.CIV.P. 26(e)(1). As expert discovery was closing, Arthrex contended on July 26, 2006 for the first time that data generated by one of its experts months ago “*may have been*” affected by a computer virus. Arthrex also asserted that it would be “supplementing” its expert reports because of this virus. But Arthrex has offered no proof to substantiate its virus allegations or to satisfy the limited supplementation exception of FED.R.CIV.P. 26(e)(1). Mitek believes that Arthrex really seeks to use these virus allegations as an excuse to redo expert discovery because it is unhappy with its experts’ performance. Permitting Arthrex to simply redo expert discovery based on an unsubstantiated claim of a computer virus, now that expert discovery is closed, will severely complicate this case and prejudice Mitek. Accordingly, it should not be permitted absent proof of this computer virus.

A memorandum in support of this motion is being filed currently herewith.

Dated: August 9, 2006

DEPUY MITEK, INC.,

By its attorneys,

/s/ Erich M. Falke

Dianne B. Elderkin

Lynn A. Malinoski

Michael J. Bonella

Erich M. Falke

WOODCOCK WASHBURN LLP

One Liberty Place - 46th Floor

Philadelphia, PA 19103

(215) 568-3100

Daniel J. Gleason (BBO #194900)

Michelle Chassereau Jackson (BBO  
#654825)

Nutter McClennen & Fish LLP

World Trade Center West

155 Seaport Boulevard

Boston, MA. 02210-2604

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.,</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom,</b>	)	
	)	
<b>Defendants.</b>	)	

**DePuy Mitek, Inc.'s Memorandum In Support of Its Motion To Preclude Arthrex, Inc. and  
Pearsalls Ltd. From "Supplementing" Their Expert Reports and Depositions**

## Table of Contents

I.	Introduction.....	1
II.	Background.....	2
A.	Nature and Stage of the Case .....	2
B.	Arthrex’s Belated Allegation of a Computer Virus .....	2
III.	Arthrex Should Not Be Permitted To Redo Expert Reports and Discovery.....	4
A.	Legal Requirements for “Supplementing” Expert Reports.....	4
B.	Arthrex Has Not Provided a Legitimate Reason for Redoing Expert Reports and Discovery .....	6
1.	Arthrex Has Not Shown That Dr. Gitis’ Report Was “Inaccurate” or “Incomplete” Due To a Virus .....	6
2.	Arthrex’s Request To Supplement Should Be Denied Unless Arthrex Can Show that Dr. Gitis Did Not Know About the Virus and Did Not Delay in Raising It .....	8
IV.	If Permitted To “Supplement,” Arthrex Should Not Be Permitted To Supplement Beyond Any Proven Inaccuracies Due To the Virus .....	9
A.	Rule 26(e)(1) Does Not Permit a Party To Redo Expert Discovery.....	9
B.	Arthrex Should Not Be Permitted To Correct Dr. Gitis’ Test Flaws Which Have Nothing Whatsoever To Do With Any Virus.....	9
C.	Arthrex Should Not Be Permitted To Try To Change Dr. Gitis’ or Dr. Mukherjee’s Deposition Testimony Which Has Nothing To Do With An Alleged Virus .....	11
D.	Arthrex Should Not Be Permitted To Simply Redo its Expert Work Because It Would Significantly Prejudice Mitek.....	13
V.	Conclusion .....	15

## Table of Authorities

### Federal Cases

<i>Akeva L.L.C. v. Mizuni Corp.</i> , 212 F.R.D. 306 (M.D. N.C. 2002) .....	6, 9
<i>Coles v. Perry</i> , 217 F.R.D. 1 (D. D.C. 2003).....	6
<i>DAG Enterprises, Inc. v. Exxon Mobil Corp.</i> , 226 F.R.D. 95 (D. D.C. 2005).....	5, 9
<i>Keener v. United States</i> , 181 F.R.D. 639 (D. Mont. 1998).....	5, 6
<i>Minebea Co., Ltd. v. Papst</i> , 231 F.R.D. 3 (D. D.C. 2005).....	4, 5
<i>Saint-Gobain Corp. v. Gemtron Corp.</i> , No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263 (W.D. Mich. May 9, 2006) .....	5, 6
<i>Schweizer v. DEKALB Swine Breeders, Inc.</i> , 954 F. Supp. 1495 (D. Kan. 1997) .....	5
<i>Sharpe v. United States</i> , 230 F.R.D. 452 (E.D. Va. 2005) .....	9
<i>Stein v. Foamex International, Inc.</i> , No. 00-2356, 2001 U.S. Dist. LEXIS 12211 (E.D. Pa. Aug. 15, 2001) .....	6
<i>White v. Cinemark USA, Inc.</i> , No. 2:04-cv-397-GEB-CMK, 2005 U.S. Dist. LEXIS 42134 (E.D. Cal. Aug. 3, 2005) .....	6

### Federal Statutes

Fed.R.Civ.P. 26(e)(1).....	4, 5, 7, 9, 11
----------------------------	----------------

## I. Introduction

Plaintiff, DePuy Mitek, Inc. (“Mitek”), requests an order preventing Defendants, Arthrex, Inc. and Pearsalls, Inc., (collectively, “Arthrex”)<sup>1</sup> from “supplementing” their technical expert reports.

With only three months to trial, Arthrex has belatedly recognized that it has serious problems with the expert testing and reports it submitted to try to prove that its accused FiberWire sutures do not infringe Mitek’s Hunter Patent. As spelled out in the July 14 Amended Supplemental Report of Mitek’s expert, Dr. David Brookstein, the methodology Arthrex’s experts used to carry out Arthrex’s “noninfringement” tests was significantly flawed, and the results were contradictory. Arthrex also has a problem in that the expert who submitted the expert report outlining the “noninfringement” tests, Dr. Gitis, and the expert who is supposed to rely on those tests and offer an opinion of noninfringement, Dr. Mukherjee, both showed at their depositions that neither could explain the significance of Dr. Gitis’ test results.

On the heels of receiving Dr. Brookstein’s Amended Supplemental Report, Arthrex informed Mitek that Dr. Gitis’ data “may have been” affected by a computer virus and that he would be re-doing his tests and issuing a new expert report (Ex. 7). These belated allegations – the 21<sup>st</sup> Century equivalent to the “dog ate my homework” excuse – are unsupported and incredible. Arthrex offers too little explanation too late, and giving Arthrex a second chance at this late date would be contrary to the rules and would be highly prejudicial to Mitek. The focus now should be on preparing for trial. Arthrex should be precluded from “supplementing” or re-doing expert reports at this late date.

---

<sup>1</sup> Arthrex and Pearsalls are jointly represented by the same counsel and have jointly submitted expert reports. Generally, Arthrex and Pearsalls have not distinguished between their defenses. Accordingly, Mitek generally uses “Arthrex” to refer to both Arthrex and Pearsalls in this motion.



## **II. Background**

### **A. Nature and Stage of the Case**

Mitek and Arthrex compete for sales of sports-medicine, medical devices. Mitek is based outside of Boston, and Arthrex is based in Naples, Florida. The other defendant in this action is Pearsalls, who manufactures and imports into the United States products for Arthrex. Pearsalls is a foreign company located in rural England.

This is a patent infringement action involving Mitek's U.S. Patent No. 5,314,446 which claims surgical sutures and suture products (Ex. 1 at 8:62-10:19). Arthrex's sale of its FiberWire sutures and suture products infringes Mitek's 446 Patent; Pearsalls' importation and sales of suture braids constitute contributory infringement.

Fact and expert discovery are closed. Claim construction briefs and dispositive motions are due this week on August 11 (D. I. 27 & June 16, 2006 Minute Order). A jury trial is scheduled to commence on November 13, 2006 (*id.*).

### **B. Arthrex's Belated Allegation of a Computer Virus**

Mitek's 446 Patent claims surgical sutures and other surgical products that have a novel construction of certain dissimilar materials braided together (Ex. 1 at 8:62-9:10). As the 446 Patent explains, the claimed sutures have enhanced properties attributable to the dissimilar materials (*id.* at 2:49-52). Arthrex specifically engineered its FiberWire suture product to be dissimilar materials braided together, with enhanced properties attributable to the dissimilar materials (Ex. 2, Expert Rpt. of Dr. David Brookstein, at ¶¶28-32; Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶27-36).

Even though the 446 Patent expressly teaches that the sutures of its invention can be coated (Ex. 1 at 6:5-17), Arthrex alleges that a coating on its FiberWire sutures somehow renders the sutures noninfringing. As Mitek understands Arthrex's argument, Arthrex alleges that

FiberWire's surface coating "materially affects" certain alleged "basic and novel characteristics of the inventions" claimed in the 446 Patent. In support of this position, one of Arthrex's technical experts, Dr. Norman Gitis, conducted a series of tests purporting to compare the properties of "coated" suture with "uncoated" suture, and reported those tests in his expert report (Ex. 4, Dr. Gitis' Report). The tests allegedly included tests for certain suture properties, including pliability, knot slippage strength, knot run down, friction, tissue drag, and chatter (*id.*). Another of Arthrex's technical witnesses, Dr. Mukherjee, reviewed and relied on Dr. Gitis' report in giving his opinion that the FiberWire sutures are non-infringing (Ex. 5, Dr. Mukherjee's Responsive Rpt., at 2, referring to Dr. Gitis report as the "reports prepared by the Center for Tribology, Inc."). Dr. Gitis' and Dr. Mukherjee's expert reports were served on March 24, 2006.

Because the 446 Patent is not about coatings, but rather about braiding certain dissimilar fiber-forming materials together, Mitek disagrees with Arthrex's position that Arthrex's sutures are non-infringing because they have a coating (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶22-54). Nevertheless, Mitek's expert, Dr. David Brookstein, spent months analyzing Dr. Gitis' tests and analyses and concluded that his work was essentially meaningless and irrelevant (*id.* at ¶¶43-52 & Ex. 6, Dr. Brookstein's Amended Supp. Rpt.). In his July 14 Supplemental Expert Report,<sup>2</sup> Dr. Brookstein opined that Dr. Gitis' methodology was significantly flawed because, *inter alia*, he did not test samples that were really "coated" against "uncoated," his testing methodology

---

<sup>2</sup> On March 28, 2006, immediately after receiving Dr. Gitis' report, Mitek requested, *inter alia*, the data underlying Dr. Gitis' tests, his test protocols, and discovery of the construction and manufacturing of the samples that he tested (Ex. 10). Despite numerous requests for this information, Arthrex's counsel was not able to produce it before rebuttal expert reports were due on April 13, 2006 (Exs. 11-14). Although Arthrex's counsel had a mid-April trial, it was not able to even produce information in its possession before April 13, 2006 (*id.*). Thus, the parties agreed that Dr. Brookstein could supplement his report after Arthrex provided the requested information (Ex. 15).

was flawed, and Dr. Gitis' test results contradicted some of Arthrex's positions (Ex. 6, Dr. Brookstein's Amended Supp. Rpt.<sup>3</sup>, at ¶¶35, 43).

Three months after Dr. Brookstein's Rebuttal Report, a month after Dr. Gitis' deposition and eleven days after Dr. Brookstein's Supplemental Report was served – but a full *four months* after Dr. Gitis had served the report now criticized by Dr. Brookstein – Arthrex informed Mitek that Dr. Gitis' data “may have been” affected by a computer virus and that he would be redoing his tests and issuing a new expert report (Ex. 7) (emphasis added). Mitek immediately requested information regarding the alleged virus and how it affected Dr. Gitis' work (Ex. 8). To date, Mitek has received no response to this letter.

On August 1, the parties discussed the issues, but were unable to resolve them. Mitek advised Arthrex that it would be filing a motion to preclude Arthrex from “supplementing” expert reports. Later that day, Arthrex informed Mitek that Dr. Gitis would be out of the country for the next couple of weeks due to an unexplained, unexpected emergency (Ex. 9).

### **III. Arthrex Should Not Be Permitted To Redo Expert Reports and Discovery**

#### **A. Legal Requirements for “Supplementing” Expert Reports**

FED.R.CIV.P. 26(e)(1) provides a “limited exception” for *supplementing* an expert's report. *Minebea Co., Ltd. v. Papst*, 231 F.R.D. 3, 7 (D. D.C. 2005). In relevant part, FED.R.CIV.P. 26(e)(1) provides that a party may “supplement” an expert report “if the party learns that in some material respect the information disclosed is incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.”

---

<sup>3</sup> On August 24, 2006, Dr. Brookstein submitted an Amended Supplemental Expert Report to correct a typographical error. In all other respects, Dr. Brookstein's Amended Supplemental Report is identical to his Supplemental Expert Report dated July 14, 2006.

Although Arthrex has characterized its intended actions as “supplementing” the Gitis report, it is clear that what it is really intending to do is “redo” the Gitis tests and the report. The Federal Rules do not contain a provision for *redoing* expert reports. *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 109-10 (D. D.C. 2005) (holding that supplementation does not permit a party to simply substitute an old report for a new one); 6 JAMES WM. MOORE ET AL., MOORE’S FEDERAL PRACTICE ¶ 26.131[2] (3d ed. 2006) (explaining that “[a] party may not use a supplemental report to disclose information that should have been disclosed in the initial report, thereby circumventing the requirement for a timely and complete report”) (Ex. 16).

Nor does Rule 26(e)(1) grant a party the right to supplement reports merely because it believes such reports would be “desirable” or “necessary.” *Minebea*, 231 F.R.D. at 7 (citing *Keener v. United States*, 181 F.R.D. 639, 640 (D. Mont. 1998)). Rather, the supplementation permitted by Rule 26(e)(1) is generally limited to the “narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report.” *Id.*; *DAG Enters.*, 226 F.R.D. at 109-110 (holding that “supplementation under the Rules means correcting inaccuracies, or filling the interstices of an incomplete report,” not substituting reports). A factor in denying requests for supplementation is whether the information was known to the party requesting supplementation before expert discovery closed.<sup>4</sup>

---

<sup>4</sup> *Minebea*, 231 F.R.D. at 7 (citing *Keener*, 181 F.R.D. at 640); *Saint-Gobain Corp. v. Gemtron Corp.*, No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (W.D. Mich. May 9, 2006) (Ex. 17) (holding that expert could not supplement where party trying to supplement could not show that the new information was unknown to it); *Schweizer v. DEKALB Swine Breeders, Inc.* 954 F. Supp. 1495, 1510 (D. Kan. 1997) (excluding supplemental report of expert containing new opinions when there was no reason the opinions could not have been expressed in the expert's original report).

**B. Arthrex Has Not Provided a Legitimate Reason for Redoing Expert Reports and Discovery**

Even if what Arthrex plans to do could properly be characterized as merely “supplementing” its expert reports, it has provided no legitimate reason for being permitted to do so. Rule 26 requires Arthrex to show that Dr. Gitis’ report was either “inaccurate” or “incomplete” based on the alleged virus. Arthrex has shown neither. Nor has Arthrex shown that the virus information was previously unknown to Dr. Gitis.

**1. Arthrex Has Not Shown That Dr. Gitis’ Report Was “Inaccurate” or “Incomplete” Due To a Virus**

According to Arthrex, the only alleged reason for redoing expert reports is that Dr. Gitis’ report “*may* be based upon data that was corrupted” (Ex. 7) (emphasis added). But an unsubstantiated allegation that a virus “*may*” have occurred is not proof that it did occur. Nor is a bare allegation of data corruption proof of an “inaccuracy” or omission that resulted from the virus. Absent proof of the virus itself and of a material inaccuracy or omission resulting from the virus, there is no justification for supplementation.<sup>5</sup>

Arthrex’s virus/corruption allegations are belied by the record evidence. Dr. Gitis’ report, on its face, shows no indication of data corruption (Ex. 4). Further, the disk containing

---

<sup>5</sup> *Saint-Gobain Corp.*, 2006 U.S. Dist. LEXIS 28263, at \*4-5 (holding that expert could not supplement where Rule 26(e)(1) not satisfied) (Ex. 17); *White v. Cinemark USA, Inc.*, No. 2:04-cv-397-GEB-CMK, 2005 U.S. Dist. LEXIS 42134, at \*9-10 (E.D. Cal. Aug. 3, 2005) (Ex. 24) (holding that there was no reason to supplement where the proponent of the report declared that the original report was neither inaccurate nor incomplete); *Coles v. Perry*, 217 F.R.D. 1, 3 (D. D.C. 2003) (striking late-filed report styled “supplemental opinion,” noting that “Fed. R. Civ. P. 26(e) does not grant a license to supplement a previously filed expert report because a party wants to”); *Akeva L.L.C. v. Mizuni Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002) (holding that Rule 26(e)(1) “does not cover failures of omission because the expert did an inadequate or incomplete preparation”); *Stein v. Foamex Int’l, Inc.*, No. 00-2356, 2001 U.S. Dist. LEXIS 12211, at \*15 (E.D. Pa. Aug. 15, 2001) (Ex. 18) (holding that a late filed affidavit was not a supplemental expert report because it does not contradict the original report in any material respect); *Keener*, 181 F.R.D. at 640 (second expert report was not a supplemental report because it was not shown that the first report was inaccurate or incomplete in some material respect).

Dr. Gitis' data works just fine. In fact, the computer disk shows, line-by-line, tens of thousands of data points that Dr. Gitis collected during his experiments and does not reflect any corruption.<sup>6</sup> A virus typically corrupts data so that it is not usable; it generally does not change data.

Not only is there nothing on the face of the Gitis Report or the underlying data to indicate corruption, but Dr. Gitis testified that he "checked the results" of his tests (Ex. 19, Dr. Gitis' Dep., at 85:12-18). He further testified that he did not "remember 100 percent, *but I am almost sure that I checked all the calculations in all the tests*" (*id.* at 85:12-18; 197:22-24) (emphasis added). Thus, the record evidence is that there was no data corruption by any virus.

Arthrex should not be permitted to redo its expert reports because, at this point, the virus is nothing more than an unproven allegation that fails to satisfy the requirements of Rule 26(e)(1).

If Arthrex is not denied, outright, the chance to redo its expert reports, it should first be ordered to make an offer of proof explaining specifically how Dr. Gitis' report was "inaccurate" or "incomplete" due to this alleged virus. Arthrex's offer of proof should include:

- proof of what the virus was;
- proof of what machines were affected;
- proof of how the virus affected the machines;
- proof of how the virus affected the data;
- proof of how the virus affected Dr. Gitis' analysis and report;
- proof of when this virus occurred;
- proof of when Dr. Gitis was aware of it; and
- an explanation of why Dr. Gitis and Arthrex delayed in raising the issue.

A bare declaration from Dr. Gitis, who is neither a computer science expert nor a virus expert, should not be accepted as proof. Rather, Arthrex's required proof should include forensic computer experts and virus experts that trace how this virus affected Dr. Gitis' work.

---

<sup>6</sup> When printed out, Dr. Gitis' data is about 1.5 to 2 bankers boxes of Excel spread sheets.



It is important that Arthrex should have to first prove a virus before Mitek is forced to investigate the veracity of these virus allegations because evaluating them will be costly to Mitek. Mitek will likely have to hire at least two experts: a forensic computer expert to analyze Dr. Gitis' allegedly infected laboratory equipment, and a computer virus expert to analyze whether and how the unidentified virus actually caused an inaccuracy. This will likely involve expert reports and depositions. This is all very expensive and time consuming and Mitek should not be forced to undergo this effort until Arthrex can establish a *prima facie* case regarding its virus.

If Arthrex presents a *prima facie* case that a virus had some material impact on Dr. Gitis' report, and if Arthrex satisfies the other requirements for supplementation, Mitek should then be afforded an opportunity to investigate the accuracies of these proofs. Only if Arthrex can prove what was affected should Arthrex be permitted to redo its work, and only then to the extent that it can prove that corruption occurred.

**2. Arthrex's Request To Supplement Should Be Denied Unless Arthrex Can Show that Dr. Gitis Did Not Know About the Virus and Did Not Delay in Raising It**

Not only has Arthrex not shown any inaccuracies due to a virus, it has not shown that Dr. Gitis' report was incomplete based on information that was not available to him when he drafted his report or before expert discovery closed. In fact, it defies credibility that a virus could be so serious, yet Dr. Gitis was not aware of it when he generated his report, or at a minimum, well before Arthrex raised the virus allegation on July 24, 2006.

If Dr. Gitis' lab had a virus and it somehow affected his work, Arthrex should have raised the issue months ago, not at the close of expert discovery. Both Arthrex and Dr. Gitis waited until after Mitek's expert, Dr. Brookstein, spent months analyzing Dr. Gitis tests. They waited until after Arthrex's technical witnesses, Dr. Gitis and Dr. Mukherjee, had been deposed in June

2006. They waited until after Mitek traveled to Pearsalls, located in the rural England countryside, at the end of June to conduct discovery on the samples that Dr. Gitis tested. Having inexplicably delayed until expert discovery was closing – over a month after Mitek completed its discovery of Arthrex’s experts – Arthrex is hard-pressed to show that any omission was based on information that was not available to it much earlier. Further, if Arthrex’s delay caused proof of this alleged virus to be lost, then it should not be permitted to supplement.

**IV. If Permitted To “Supplement,” Arthrex Should Not Be Permitted To Supplement Beyond Any Proven Inaccuracies Due To the Virus**

**A. Rule 26(e)(1) Does Not Permit a Party To Redo Expert Discovery**

Mitek is concerned that this virus is nothing more than a trumped-up excuse for redoing expert reports that Arthrex now recognizes are flawed. At great expense, Mitek uncovered numerous deficiencies in Dr. Gitis’ testing and expert report. But there is no way that these deficiencies could ever be attributed to a virus, even if the existence of a virus were proven. As explained above, Rule 26(e)(1) is not a provision for redoing expert reports under the guise of an unsubstantiated virus.<sup>7</sup> Thus, if Arthrex is allowed to “supplement” its reports at all, that supplementation should be limited to those parts of Dr. Gitis’ testing that Arthrex can prove were actually corrupted by the alleged virus.

**B. Arthrex Should Not Be Permitted To Correct Dr. Gitis’ Test Flaws Which Have Nothing Whatsoever To Do With Any Virus**

Dr. Brookstein, Mitek’s expert, has criticized Dr. Gitis’ work for testing samples that had too many variables. As a result, no cause and effect relationship can be drawn between FiberWire’s coating and the outcome of the tests (Ex. 6, Dr. Brookstein’s Supp. Rpt., at ¶¶5-10).

---

<sup>7</sup> *Sharpe v. United States*, 230 F.R.D. 452, 462 (E.D. Va. 2005) (denying supplementation where party sought to correct remedy experts’ faulty opinions); *DAG Enters.*, 226 F.R.D. at 109-110 (holding that supplementation does not permit a party to simply substitute an old report for a new one); *Akeva*, 212 F.R.D. at 310 (holding that Rule 26(e)(1) “does not cover failures of omission because the expert did an inadequate or incomplete preparation”).

Selecting samples has nothing whatsoever to do with an alleged computer virus. Dr. Gitis obtained those samples from Arthrex's counsel (Ex. 4 at 2, Section 3; Ex. 19, Gitis Dep. at 94:16-20), and Arthrex's counsel obtained the samples from Pearsalls (Ex. 20, PR08458, PR088460). Selection of materials were human decisions and wholly irrelevant to any alleged virus. Thus, Arthrex should not be permitted to use this virus as an excuse for generating new tests.

Further, Dr. Gitis' testing methodology has problems that cannot be attributed to a computer virus. For example, Dr. Gitis purported to conduct a "pliability" test (Ex. 4 at 2-4, Section 5). But Dr. Gitis' so-called "pliability test" was a tension test, not a pliability test (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶45-52; Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶11-17). After being cross-examined, even Dr. Mukherjee, Arthrex's other expert, admitted that Dr. Gitis did not measure pliability:

- Q. Did you approve the pliability tests that Dr. Gitis did before he did it?
- A. He's the authority. He decided on it and -- and we just did the -- *we didn't measure pliability, all right?* That is the extent of conversation I had. He decided the procedure and the technique.

(Ex. 21, Dr. Mukherjee's Dep., at 425:2-9) (emphasis added) (objection omitted). Further, Dr. Gitis' assumptions underlying his "pliability" test were flawed and his test was improperly conducted (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶45-52; Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶11-17). These errors have nothing whatsoever to do with an alleged virus.

Dr. Gitis also incorrectly measured the suture diameter with a mechanical device (Ex. 6, Dr. Brookstein's Supp. Rpt., at ¶¶18-22), which has nothing to do with software. Further, during his tissue drag tests, Dr. Gitis did not control testing parameters that affect the outcome of his

tests (*id.* at ¶44). For example, when asked how he controlled the tension force that affects the measured drag or friction, Dr. Gitis admitted that “[w]e didn’t control it” (Ex. 19, Dr. Gitis’ Dep., at 273:2-5). For his friction test, Dr. Gitis admitted that he did not measure the clamping force on the suture (*id.* at 249:22-24), which also affects the measured friction values.<sup>8</sup>

None of these errors can be attributable to any virus. Arthrex should not be permitted to fix non-virus-caused errors in any of its expert reports.

**C. Arthrex Should Not Be Permitted To Try To Change Dr. Gitis’ or Dr. Mukherjee’s Deposition Testimony Which Has Nothing To Do With An Alleged Virus**

Likewise, Arthrex should not be permitted to change or “muddy up” Dr. Gitis’ or Dr. Mukherjee’s deposition testimony under the guise of a supplemental expert report. Dr. Gitis’ and Dr. Mukherjee’s deposition statements are not “inaccuracies” within the meaning of Rule 26(e)(1).

For example, Arthrex has a problem in the fact that it has no expert who can explain the relevance of Dr. Gitis’ tests. Dr. Gitis admitted that his role was limited to conducting tests and reporting the test results, and he could not attribute any meaning to the test results:

- Q. Have you been asked to provide opinions, or have you just been asked to perform certain tests and provide the test results?
- A. Not -- I have not been asked to provide any opinions, only to test and to produce test results.
- Q. Were you asked to draw any opinions or conclusions about what caused the difference in the results?
- THE WITNESS: I was asked by you today, but I was never asked by Dickstein Shapiro.

---

<sup>8</sup> Dr. Gitis’ testing methodology has other flaws; Mitek has provided only a few examples here.

(Ex. 19, Dr. Gitis Dep., at 12:2-7, 312:6-11 (objection omitted); *see also* 62:7-14, 63:9-13). It was apparently Dr. Mukherjee's role to explain the meaning and relevance of Dr. Gitis' tests, but he admitted that he was not an expert in explaining the meaning of Dr. Gitis' tests and test results:

Q. Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?

A. Not really.

(Ex. 21, Dr. Mukherjee's Dep., at 452:16-19; *see also* Ex. 21 at 423:17-424:1; 431:6-433:17; 442:14-443:10; 444:11-17; 446:22-447:7; 450:2-21; 451:7-16; 451:24-452:4; 454:11-455:6; 456:2-9; 457:11-17 (stating that he could not explain Dr. Gitis' data or tests)). Thus, based on Arthrex's experts' deposition testimonies, neither of its technical experts is qualified to explain the significance of Dr. Gitis' tests.<sup>9</sup>

Further, based on Dr. Gitis' deposition testimony, Arthrex has no witness who can even explain many of Dr. Gitis' tests because Dr. Gitis admitted that he did not know how they were conducted. For example, with respect to his knot-run down test (another type of friction test), he testified that he did not know how the end of the suture was controlled (which is important for measuring friction):

Q. Okay. What happens to the lower one?  
What happens to the other end?

A. I don't remember. We didn't describe here, and I don't remember.

Q. Well, how is the knot running down? I mean, what's holding the other end? Something's got to hold the other end, right --

A. Right.

Q. -- if it's a run-down test.

A. Right. Sorry, I don't remember.

---

<sup>9</sup> This is reason enough for not permitting Arthrex to redo Dr. Gitis' work because his new work would be irrelevant; there is no Arthrex expert qualified to discuss its significance.

Q. So you can't exactly tell me how this test was done?

A. I have to think about it. I don't remember.

(Ex. 19, Dr. Gitis Dep., at 236:23-237:11). Similarly, Dr. Gitis had no idea how the suture “chatter” data that he reported were determined:

Q. Sure. One thing you could do, I just don't understand how the computer is doing this. One thing you could do is you could take this high point to the next low point, high point to low point, and you figure out that difference for each time and average them; or you can figure out what the high point was, the average high point and the average low point, and take the difference between those two.

A. Yes.

Q. Or there could be some other way you could do this. I don't know.

A. Yeah, I do not remember. I'm sorry.

Q. You don't know?

A. No.

(Ex. 19, Dr. Gitis Dep., at 268:16-269:5). Thus, lacking a witness who can explain Dr. Gitis' tests, Mitek believes that Arthrex wishes to redo the tests and generate new and different deposition testimony. But it should not be permitted to redo its expert reports and expert depositions under the guise of an unsubstantiated virus.

**D. Arthrex Should Not Be Permitted To Simply Redo its Expert Work Because It Would Significantly Prejudice Mitek**

Permitting Arthrex to redo expert discovery would significantly prejudice Mitek for several reasons. Mitek expended significant resources analyzing Dr. Gitis' work. For example, Mitek's expert Dr. Brookstein spent a significant amount of time analyzing Dr. Gitis' work, preparing a report regarding it, and being deposed about it. His work was extensive. He analyzed Dr. Gitis' testing methodology for six tests, namely pliability, knot slippage strength, knot run-down, friction, chatter, and tissue drag (Ex. 3, Dr. Brookstein's Rebuttal Rpt., at ¶¶43-



52; Ex. 6, Dr. Brookstein's Amended Supp. Rpt.). He also analyzed Dr. Gitis' data from all of the tests which included millions of data points (Ex. 6, Dr. Brookstein's Amended Supp. Rpt.).

Mitek's counsel also spent a significant amount of time analyzing Dr. Gitis' work and conducting discovery regarding his work, including expert depositions. This discovery included a deposition in rural England at Pearsalls to discover the exact nature of the "coated" and "uncoated" sutures tested by Dr. Gitis. Arthrex and Pearsalls refused to answer interrogatories about how the sutures were made, which could have made the depositions unnecessary (Exs. 22-23).<sup>10</sup>

Mitek would be further prejudiced by allowing Arthrex to redo expert reports because of the current posture of this litigation. The November trial date – which Mitek sorely wants to hold – is only three and a half months away. Mitek needs to focus now on claim construction briefing, dispositive motions, and trial preparation. If Arthrex is allowed to redo the Gitis tests, Mitek must start all over again, having its expert analyze the "new" tests and deposing Dr. Gitis and Dr. Mukherjee, not to mention taking the discovery it would be entitled to take to verify the virus allegations in the first place.

If Arthrex really thought it had proof of a virus which would justify a redo of its expert reports, it should have come forward *immediately* with proof of the virus, proof that data were corrupted by the virus, proof of how the corruption occurred, and proof of when Dr. Gitis uncovered the virus. Instead, Arthrex now says that Dr. Gitis is unavailable for several weeks, so the parties will be that much closer to trial – and already into dispositive motion briefing – before any explanation can be offered by Arthrex.

---

<sup>10</sup> Arthrex would only answer the interrogatories if Mitek gave up the deposition (Exs. 22 & 23). But Mitek could not agree to that condition in advance of receiving an interrogatory answer because litigants have been known to not completely and precisely answer interrogatories.

At this stage of the case, and under the circumstances presented, permitting Arthrex to scrap Dr. Gitis' work and start over at Mitek's expense is simply not fair and should not be permitted.

At the very least, if Arthrex is permitted to move forward as it proposes, Mitek should be awarded attorney fees, expert fees, and costs associated with dealing with Arthrex's errors. If Arthrex proves that a virus did indeed exist and did indeed corrupt some of Dr. Gitis' data, *and* that Dr. Gitis and Arthrex did not delay in bringing this information forward, Mitek should be awarded fees and costs for taking new expert discovery. Mitek should not be financially penalized for Arthrex's and Dr. Gitis' carelessness in failing to timely recognize the alleged virus. If Arthrex's allegations of a virus and corruption are not substantiated, Mitek should be awarded fees and costs associated with evaluating Arthrex's virus allegations, including its fees and costs associated with this motion.

## **V. Conclusion**

At this point, Arthrex's virus story is nothing more than an unsubstantiated allegation. Arthrex should not be permitted to redo its expert reports and prejudice Mitek simply because Arthrex and Dr. Gitis think that they could have done a better job.

If Arthrex is permitted to try to prove that a virus corrupted its expert data, it should be required to come forward with an offer of proof of: what the virus was, what machines in Dr. Gitis' lab were affected by the virus, how the virus affected the machines, how the virus affected data in Dr. Gitis' report, when the virus occurred, when Dr. Gitis or his lab learned of the virus, and when Arthrex learned of the virus. If the Court deems the offer of proof sufficient, Mitek should then have the opportunity to investigate the virus allegations, including taking discovery and having its own computer forensic experts evaluate Arthrex's allegations.

If, ultimately, Arthrex is permitted to supplement any portion of Dr. Gitis' and Dr. Mukherjee's reports, that supplementation should be limited to parts of the report that were directly affected by the alleged virus contamination.

Finally, Mitek respectfully requests an award of fees and costs, as appropriate, for having to address these issues.

Date: August 9, 2006

/s/ Erich M. Falke

Dianne B. Elderkin  
Lynn A. Malinoski  
Michael J. Bonella  
Erich M. Falke  
Woodcock Washburn LLP  
One Liberty Place 46<sup>th</sup> Floor  
Philadelphia, PA. 19103  
215-568-3100

Daniel J. Gleason (BBO #194900)  
Michelle Chassereau Jackson (BBO  
#654825)  
Nutter McClennen & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA. 02210-2604

### CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

**DePuy Mitek, Inc.'s Motion to Preclude Arthrex, Inc. and Pearsalls Ltd. From  
"Supplementing" Their Expert Reports and Depositions; and**

**DePuy Mitek's Memorandum In Support of Its Motion To Preclude Arthrex, Inc.  
and Pearsalls Ltd. From "Supplementing" Their Expert Reports and Depositions**

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber  
Dickstein Shapiro  
1825 Eye Street, NW  
Washington, DC 2006  
[saberc@dicksteinshapiro.com](mailto:saberc@dicksteinshapiro.com)

Raymond P. Ausrotas  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109  
[rausrotas@toddweld.com](mailto:rausrotas@toddweld.com)

Dated: August 9, 2006

/s/ Erich M. Falke  
Erich M. Falke

# **EXHIBIT 24**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)	
a Massachusetts Corporation	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil No. 04-12457 PBS
	)	
Arthrex, Inc.	)	
a Delaware Corporation and	)	
	)	
Pearsalls Ltd.,	)	
a Private Limited Company	)	
of the United Kingdom,	)	
	)	
Defendants.	)	

**Rebuttal Expert Report of Dr. David Brookstein**

**I. Background Information**

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

**II. Summary of Opinions**

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.



4. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that FiberWire’s coating does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

5. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that the nylon in TigerWire does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

6. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that FiberStick’s adhesive does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

7. The reverse doctrine of equivalents does not prevent infringement.

8. I disagree with Dr. Mukherjee that FiberWire’s benefits, which Arthrex promotes, are almost exclusively due to the UHMWPE in FiberWire.

### **III. If PE Is Construed Not to Include UHMWPE, FiberWire Still Infringes Under the Doctrine of Equivalents**

9. As I explained in my previous report, if “PE” as claimed in the 446 Patent is construed not to include “UHMWPE,” there is infringement under the doctrine of equivalents because the differences between UHMWPE and “PE” are insubstantial. Dr. Mukherjee has expressed opinions to the contrary. But I disagree with him for at least the following reasons.

10. As one basis for his opinion of substantial differences between “PE” and UHMWPE, Dr. Mukherjee opines that the 446 Patent describes the first fiber-forming materials as “lubricous but relatively weak” and alleges that the first fiber-forming materials are different than UHMWPE, which is known to have certain strength properties (Mukherjee Res. Report at 15). I disagree because the 446 Patent does not describe the first fiber forming materials as “lubricous but relatively weak.” In fact, it never describes the first fiber-forming materials, including “PE,” as

“weak.” Rather, in a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting “as lubricating yarns,” but not “weak” yarns (Ex. D at 4:11-12). UHMWPE is consistent with the description of the first fiber-forming materials in the 446 Patent. The 446 Patent describes that, in a preferred embodiment, the first yarns act as lubricating yarns (Ex. D at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. I at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be “non-absorbable polymers” (Ex. D at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. D at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent’s description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56. Therefore, I disagree with Dr. Mukherjee’s opinion that the 446 Patent describes the first fiber-forming materials as “weak,” and I also disagree that the differences between UHMWPE and PE are substantial.

12. I disagree that the 446 patent describes the first fiber-forming materials as “weak,” as Dr. Mukherjee states (Mukherjee Res. Report at 15), for additional reasons. Dr. Mukherjee states that the 446 Patent describes the first fiber-forming materials as being “weak.” But this is incorrect. For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks’ Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd

(Ex. J). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. K at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 mNtex<sup>-1</sup> (Ex. L). Thus, certain polyethylene and polypropylene fibers are not “weak” in tensile strength. Thus, I disagree with Dr. Mukherjee’s statement that the first-fiber forming materials are all “weak.”

13. Dr. Mukherjee seems to indicate that the first fiber-forming materials are all necessarily “weak” in tension when compared to the second fiber-forming materials. But this is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks’ Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. J). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 mNtex<sup>-1</sup> (Ex. L). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describes the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. M; see also Ex. N). Consequently, the first fiber-forming materials are not all “weak” in tension in

comparison to the second fiber-forming yarns, and I disagree with Dr. Mukherjee's assertion that they are.

14. As another basis for his opinion of substantial differences, Dr. Mukherjee opines that the differences between the claimed "PE" (if PE does not include UHMWPE) and UHMWPE are substantial because the claimed second fiber-forming materials are "added for strength" and UHMWPE is added to increase FiberWire's strength. I understand that the relevant comparison is between PE and UHMWPE, not between the claimed second fiber-forming materials and UHMWPE. Thus, I am not sure why Dr. Mukherjee is comparing the second fiber-forming materials to UHMWPE. Nevertheless, I disagree with his statement that FiberWire's construction is the opposite of what is described in the 446 Patent. The 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. D at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. I at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. D at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. I at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,<sup>1</sup> of the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot.

---

<sup>1</sup> I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test (*see, e.g.*, Ex. O). I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Ex. P, Q. Knot holding strength is an indication of knot security. The 446 Patent describes another exemplary knot security test (Ex. D at 6:36-44).

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with polyester (Ex. R at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. I at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester.

17. Dr. Mukherjee further opines that the differences are allegedly substantial between "PE" (if PE does not mean UHMWPE) and UHMWPE, as used in FiberWire, because UHMWPE is what makes FiberWire so strong (Mukherjee Res. Report at 16). I disagree. As explained above, although one might expect that UHMWPE provides certain strength attributes to FiberWire, namely, tensile strength, the PET adds certain strength characteristics as well, including knot holding strength. Notably, Arthrex discarded the idea of using a braid of just UHMWPE because it had poor knot holding strength characteristics, and braided PET with UHMWPE to increase the knot holding strength.

18. In support of his opinion regarding substantial differences, Dr. Mukherjee also performs a function/way/result analysis. I also disagree with this analysis. Dr. Mukherjee states that the "function" performed by the claimed first fiber-forming materials is "to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mukherjee Res. Report at 16). I disagree. The 446 Patent does not describe the function of the claimed first-fiber forming materials as "detract[ing] from strength." I disagree with Dr. Mukherjee's opinions regarding "detract[ing] from strength" for the same reasons that I stated above with reference to his opinions that the 446 Patent describes the first-fiber forming materials as "weak." Further, I disagree that his reference to column 4, lines 42-54, and a



variation of a single embodiment of a PTFE/PET braid is a statement that the first fiber-forming materials are “too weak for most suture applications” (Mukherjee Res. Report at 7). This section of the 446 Patent describes variations of single embodiment and does not discuss the use of the first fiber-forming materials in “most suture applications.”

19. Nevertheless, even if Dr. Mukherjee is correct about the “function” of the claimed first fiber-forming materials, UHMWPE, as used in FiberWire, performs the function of adding “lubricity with the recognition that these materials will detract from the strength of the resulting suture.” UHMWPE is a lubricous material that adds lubricity to the FiberWire braid (Ex. I at 52:24-53:1). Also, it is recognized that UHMWPE, due to its lubricity, detracts from certain strength characteristics, including knot holding strength (*see above*, Ex. R at 1:19-21; Ex. I at 104:9-15).

20. Although Dr. Mukherjee refers to the “way” and the “result” of the claimed first fiber-forming material, he never defines what they are. For example, Dr. Mukherjee states that the “result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different.” But he does not provide his opinion regarding the “result” attributable to the claimed first fiber-forming materials and the “way” the first-fiber forming materials perform their function. Nevertheless, I disagree with his opinion that the “result” of using UHMWPE in FiberWire is limited to increasing strength. It also adds lubricity which enhances other FiberWire properties such as handleability. Also, he seems to attribute all of FiberWire’s strength properties to UHMWPE. I disagree with this opinion. PET also contributes to FiberWire’s strength properties, namely knot holding strength properties (Ex. R at 1:19-21,29; 2:50-52; Ex. I at 104:9-15). Further, even if FiberWire’s function is increasing tensile strength,

it is my opinion that the first fiber forming materials, such as PP, function to add tensile strength. Therefore, the differences are insubstantial.

21. Dr. Mukherjee disagrees with my opinion regarding equivalents because it is too broad. I believe that he misunderstands my opinion. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

**IV. Under Dr. Mukherjee's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent**

22. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. Dr. Mukherjee opines that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18, Section VI.D.). According to Dr. Mukherjee, FiberWire's coating, TigerWire's nylon visual marker strand, and FiberStick's adhesive, each provide a "material" affect on this novel and basic characteristic that precludes infringement (Mukherjee Res. Report at 22, 30, 31). I disagree with Dr. Mukherjee's opinion and address each of his three points below.<sup>2</sup>

---

<sup>2</sup> Mr. Grafton's testimony and Arthrex's 234 patent support my opinion regarding the equivalence of UHWMPE and PE if "PE" is defined not to include UHMWPE as well as my opinion that there is no material affect on the novel and basic characteristics as set forth in my previous report for the reasons set forth herein. For example, they show that the differences are insubstantial because UHMWPE provides lubricity and PET provides knot holding strength.

**A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them**

23. According to Dr. Mukherjee, the novel and basic characteristics are “a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties” (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a “material” affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

**1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them**

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface “lubricant” (Mukherjee Res. Report at Ex. 16).

25. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. I at 52:24-53:7). The homogeneous UHMWPE braid was too lubricous to "hold a knot" (Ex. I at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. I at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (Ex. I at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. S). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. S; Ex. I at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

- Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
- A. Yes.
- Q. Yes?
- A. Yes.
- Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to

reduce the knot slippage?

A. Yes.

Q. And when you say knot slippage, we're referring to this knot security test?

A. Yes.

Q. So are we using the terms knot slippage and knot security interchangeably here?

A. You are, yes.

Q. In your testimony?

A. Yes.

Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. I at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. I at 68:25-70:13). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

26. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr.

Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the Ethicon sample)" (Ex. HH) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. HH). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

- Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?
- A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
- Q. Wait a second. You said optimization of two materials.
- A. (Witness nods head affirmatively).
- Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
- A. During -- during the -- during that period of time, yes.
- Q. So you were balancing off the properties of each material to try to get the optimum properties --
- A. Tensile strength.
- Q. To get the optimum tensile strength?
- A. (Witness nods head affirmatively).
- Q. What about knot security?
- A. Yes.
- Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
- A. Yes.
- Q. Any other properties? Knot tiedown?
- A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
- Q. So you were varying type and proportion of the



materials to optimize all these properties in the product?

A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?

A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasurable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed<sup>3</sup> and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

---

<sup>3</sup> Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

28. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

29. Dr. Mukherjee opines that the SEM's attached to my expert report are "too unclear to draw any conclusions from them" (Mukherjee Res. Report at 30). But Dr. Mukherjee concludes based on these SEM's that the "coating has permeated into the braid" (Mukherjee Res. Report at 30). I do not understand how Dr. Mukherjee can say the SEM's are "too unclear to draw any conclusions" then make conclusions from the very same "unclear" micrographs.

30. I note that Dr. Mukherjee does not opine on the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, he seems to opine that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as he defined the novel and basic characteristics. Rather, the relevant issue as he framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

**2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic**

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to *further* improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. *Most preferably*, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating *may be* eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

is shown by its product development (Ex. I at 68:25-70:15). The 446 Patent teaches “to tailor” the physical braid properties “by varying the type and proportion of each of the dissimilar fiber forming materials used” (Ex. D at 2:59-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. I at 68:25-70:15). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. D at 6:9-10).

Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can “*further*” improve the handleability of the suture (Ex. D at 6:5-18) (emphasis added). According to Dr. Mukherjee, FiberWire’s coating further improves handleability (Mukherjee Res. Report at 22-23). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. D at 6:11-13). As shown by the SEM’s of the FiberWire, the fibers are not bonded together (Mukherjee Res. Report at Ex. 20 and Exs. E-G). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

35. I further disagree with Dr. Mukherjee’s focus on FiberWire’s coating with reference to defining what is “material” because the 446 Patent is not about “coating” or eliminating “coatings.” Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. D at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (Ex. D at 1:32-43), a PTFE coating (Ex. D at 1:43-54), a monofilament like surface on a multifilament braid (Ex. D at 1:55-



3:2), and an elongated core (Ex. D at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (Ex. D at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

36. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties “attributable to the specific properties of the dissimilar fiber-forming materials” (Ex. D at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be “improved” by a coating (Ex. D at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent’s description of the invention shows that it does not consider coating, as used on FiberWire, to have a “material” effect on the basic and novel characteristics of the claimed suture.

### **3. To The Extent That I Understand Dr. Mukherjee’s Tests, They Are Irrelevant or Inconclusive**

#### **a) Dr. Mukherjee’s Tests Are Irrelevant**

37. I note that Dr. Mukherjee opines that “coating materially affects handleability,” “knot security and knot strength” (Mukherjee Res. Report at 22 and 27). But he never opines on whether the coating materially affects the basic and novel characteristic that he attributes to the 446 Patent, namely two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. According to Dr.

Mukherjee, FiberWire's coating affects certain individual suture properties. But the novel and basic characteristics that he attributes are not just individual suture properties. Rather, they are the benefits of braiding dissimilar yarns to improve one property (*e.g.*, handleability) without significantly sacrificing others (*e.g.*, physical properties). As explained above, FiberWire's braided construction has these benefits. Accordingly, any purported affect by FiberWire's coating cannot be considered material in the context of the invention.

38. Dr. Mukherjee seems to rely on the 446 Patent's statement about preferred embodiments for his rationale that a coating will materially affect the basic and novel characteristics of the invention. But he misstates the statement upon which he relies and therefore incorrectly defines material effects. The 446 Patent states that "in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional *homogeneous* fiber braids, without sacrificing physical strength or knot security" (Ex. D at 2:62-66) (emphasis added). Thus, the 446 Patent was discussing improved properties relative to *homogeneous* braids, not relative to *uncoated heterogeneous* braids of dissimilar yarns. Dr. Mukherjee ignores the reference to the homogeneous braid.

#### **b) Dr. Mukherjee's Testing and Analysis Is Flawed**

39. Dr. Mukherjee relies on Pearsalls' knot strength data (Mukherjee Res. Report Ex. 25), testing performed by Arthrex (Mukherjee Res. Report Ex. 19), testing performed by CETR (Mukherjee Res. Report Ex. 20), and "drape tests" performed by him and Dr. Burke (Mukherjee Res. Report at 27). I do not have sufficient information to fully analyze all of these tests. For example, I do not have information sufficient to determine whether the only difference between the tested samples was coating, how the samples were manufactured, the parameters of the test specifications, and whether the reported data was the complete data obtained from any and all tests performed. Nevertheless, I have formed opinions to the extent that I can, based on the

limited information with which I have been provided. Also, I note that CETR and Dr. Mukherjee appear to have analyzed and tested only FiberWire size #2 and appear to have applied that analysis without any explanation to all FiberWire products.

**(1) Pearsalls' Knot Pull Strength Tests Show No Material Change in Knot Pull Strength**

40. Dr. Mukherjee relies on Pearsalls' knot pull strength data summarized in Exhibit 25 to his Responsive Report for his opinion that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29). Exhibit 25 to Dr. Mukherjee's Responsive Report is a listing of the average knot pull strength per batch at the "dye" and "measure" stages. Dr. Mukherjee concludes from this data that the coating causes knot pull strength to materially increase. As I understand the data, the "dye" column is the average knot pull strength of a FiberWire batch that did not undergo the coating process that I observed at Pearsalls, and the "measure" column is the average knot pull strength of FiberWire that underwent the coating processes (Ex. U at 47; 1-23 Exs. Y and Z). This data appears to show that, in a significant number of instances, the measured knot pull strength *decreased* from the dye to the measure stage and therefore decreased after coating was applied to the suture. Also, at times, the measured knot pull strength stayed exactly the same. Thus, I do not know how Dr. Mukherjee can conclude from data, a significant amount of which is contradictory, that coating causes an increase in knot pull strength. He provides no explanation for this contradiction. Also, it is not clear why he necessarily attributes the change in knot pull strength to be due to coating. He fails to consider the inherent differences in tying knots, which can affect results, manufacturing differences between the "dye" and "measure" samples, and the known large variability in testing textile properties. Mr. Hallet from Pearsalls even explained that variations in the data, which Dr. Mukherjee relies upon, can be due to testing differences, not the material, and the variations in

the data were not really variations (Ex. U at 244:4-6; 348:22-349:6). To the extent that Dr. Mukherjee is relying on the final “average” computed in Ex. 25, that is improper.

41. I further disagree that Dr. Mukherjee can conclude from Pearsalls’ knot pull strength data that FiberWire’s coating materially affects FiberWire’s knot pull strength (Mukherjee Res. Report at 28-29) because he ignores entire sections of relevant data. Pearsalls’ normal practice is to perform knot pull strength testing at three stages of manufacturing, namely, the “dye,” “intermediate,” and “measure” stages. But Dr. Mukherjee wholly ignored the “intermediate” test stage data. The “intermediate” test stage data shows some of the flaws in his analysis. I understand that the suture that is tested during the “intermediate” and “measure” stage has not had any change in materials or undergone different processing (Ex. U at 348:5-13). Therefore, the knot pull strength should not change for a given batch between the “intermediate” and the “measure” stages. But, as summarized in Exhibit AA, Pearsalls’ testing shows that the measured knot pull strength was generally not the same at the intermediate and measure stages. Because Pearsalls measured “differences” in knot pull strength between the “intermediate” and “measure” stages, when one would have expected it to stay the same, it would not be correct to conclude that there was in fact a change in knot pull strength between the “intermediate” and “measure” stages. Likewise, absent some explanation, it is not correct to conclude that the knot pull strength is “changing” between the “dye” and “measure” stages. Rather, Pearsalls’ tests show that the knot pull strength basically stays the same before and after coating and that variations are probably due to testing differences, such as how the knot was tied. In fact, Mr. Hallet was asked why, for some batches, the average knot pull strength stayed about the same between the “dye” and “measure” stages, but went up at the “intermediate” stage (Ex. U at 341:16-344:25; Ex. BB). Mr. Hallet stated that the differences were probably due to the “operator” or the way the knot

was tied (Ex. U at 343:3-12). Also, Mr. Hallet testified that some changes were not really changes and were considered “about the same” (Ex. U at 344:22-25; Ex. CC). Further, when asked why, for one batch, the average knot pull strength went from 14.83 at the “intermediate” stage to “16.87” at the measure stage, Mr. Hallet attributed it to the “operator” (Ex. U at 346:21-347:1). Further, after reviewing the variations in some batches between the dye, intermediate, and measure stages, Mr. Hallet concluded that the data does not really show any variations in average knot pull strength:

Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the other?

A Yes.

MR. BONELLA: That's correct

A Yes.

(Ex. U at 348:22-349:6) (objection omitted). Thus, based on my review of Pearsalls' data and Mr. Hallet's explanation of the source of the data, I disagree with Dr. Mukherjee's opinion that he can conclude from the data in Exhibit 25 to his report that FiberWire's coating increased FiberWire's knot pull strength. If anything, Pearsalls' data show that FiberWire's coating has no material effect on knot pull strength.

## **(2) Arthrex's “Knot Tiedown” Test Is Inconclusive**

42. With respect to Arthrex's “knot tiedown” test (Mukherjee Res. Report at Ex. 19), I am unable to draw any definitive conclusions from these tests because Dr. Mukherjee has not provided information about specifically which samples were tested. Also, with respect to Arthrex's “knot tiedown” test, I believe the test is not proper for the reasons expressed by Dr. Hermes.

**(3) CETR's Tests Are Flawed and Inconclusive**

43. Dr. Mukherjee relies on the CETR tests. But the CETR report does not explain what was tested other than “two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated.” Without further information about the construction, manufacturing, processing, and handling of the samples, I cannot completely comment on the CETR tests. Further, the testing methodology is not completely clear from the CETR report. Thus, I cannot fully comment on the tests that CETR conducted.

44. Even assuming that the only difference between the two tested samples is coating, the tests are also inconclusive for the following reasons. Dr. Mukherjee uses the CETR “pliability test” to determine the effect of coating on pliability. But the “pliability test” described in section 5 of the CETR report, and the data derived from this test, are flawed for at least three reasons: (i) the purported “pliability” test uses a *tensile* test to imply pliability; (ii) the “pliability” test incorrectly assumes that *multifilament* FiberWire acts as a *monofilament*; and (iii) the “pliability” assumes a circular cross-section and a constant diameter of the suture. I address each of these errors below.

45. The test described in section 5 of the CETR report is a *tensile* test in which the FiberWire samples were not bent; it is not a *bending* test. It is basic mechanical and textile engineering that tensile tests generally cannot be used to determine bending properties in and of themselves. Typically, a tensile test places a sample in tension by extending it to a given strain level and measuring the dependent variable, tension. In contrast, a typical bending test applies a bending moment to a specimen, measures the amount of deflection in response to the bending moment, and determines from this data a bending modulus or bending rigidity. A tensile test can be used to determine the bending modulus only in the unique circumstance when the material that makes up the specimen's tensile and compressive moduli are equal and the material is monolithic, such



as certain monofilaments. By using a tensile test to determine bending rigidity, CETR assumes that coated FiberWire's tensile and compressive moduli are equal and uncoated FiberWire's tensile and compressive moduli are equal. Neither CETR nor Dr. Mukherjee provided any basis for this assumption. Without testing to prove that this assumption is correct or an explanation as to why it can be assumed, the "pliability" tests conducted by CETR are flawed.

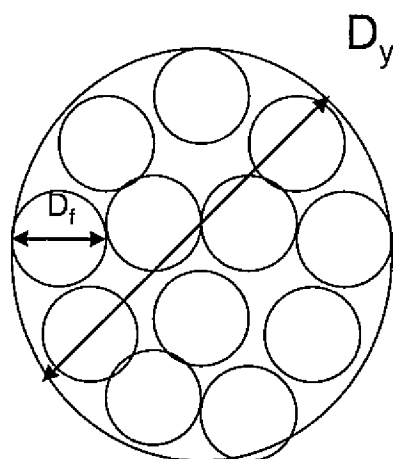
46. The second reason the CETR "pliability" test is flawed is because it incorrectly assumes that *multifilament* FiberWire is a *monofilament*. CETR used the test method advanced in the Rodeheaver paper (Mukherjee Res. Report at Ex. 13) to determine FiberWire's pliability. But the mathematical relationship used by Rodeheaver to determine pliability assumes that the tested suture is a *monofilament* (Mukherjee Res. Report at Ex. 13 at 528). By assuming a monofilament structure, CETR simplistically assumes that a multifilament suture's pliability can be determined by measuring the tensile modulus, measuring suture diameter, and determining the moment of inertia of the suture. But FiberWire is a *multifilament* suture. To determine the bending rigidity of a multifilament textile structure, such as a suture, using the Rodeheaver equation is erroneous. It is well known in the textile field that a multifilament structure's bending rigidity is proportional to the number of filaments, the modulus of elasticity, the fiber-to-fiber mobility and *the individual moment of inertia of each filament*.<sup>4</sup> In other words, the fiber-to-fiber mobility of the multifilament structure will affect the effective structural moment of inertia. Therefore, the Rodeheaver equation cannot be used to determine the pliability for FiberWire.

---

<sup>4</sup> *Mechanics of Elastic Performance of Textile Materials, Part XIV: Some Aspects of Bending Rigidity of Singles Yarns*, Platt, M., Klein, W. and Hamburger, W., Textile Research Journal, August 1959 pp. 611-627 (Ex. DD).

47. To understand the errors in Dr. Mukherjee's analysis, consider three example structures and how their bending strength or pliability can be determined. First, consider a monofilament of constant material (and assuming an equal compressive and tensile moduli) and cross-sectional circular shape ("monofilament"). The Rodeheaver test is applicable to such a monofilament structure. Second, consider a multifilament which has total freedom of inter-fiber movement during bending ("multifilament"). Such a multifilament's bending properties can be understood with reference to the 1959 seminal paper by Platt, Klein and Hamburger (Ex. DD). As Platt et al. describe, for a multifilament having complete freedom of fiber movement the product of the bending modulus ( $E$ ) and the moment of inertia ( $I$ ) of a yarn is proportional to  $N_f E_f I_f$  where  $N_f$  refers to the number of individual fibers,  $E_f$  refers to the individual fiber modulus, and  $I_f$  refers to the moment of inertia of an individual fiber. Third, consider a multifilament that does not have total freedom of inter-fiber movement during bending. The monofilament and multifilament (having complete fiber mobility) can be considered two extreme conditions with the multifilament not having complete freedom of fiber movement being between the other two conditions. Because FiberWire's structure is a braided multifilament, there cannot be complete freedom of fiber movement.

48. To understand the error in Dr. Mukherjee's analysis, I will contrast a hypothetical monofilament structure with a hypothetical multifilament with complete freedom of inter-fiber movement with reference to the Figure below (each multifilament acts independent of its neighboring filament).



Assume  $4 \cdot D_f = D_y$ . For a monofilament type structure, the moment of inertia would be  $\pi D_y^4 / 64$ , which is the equation used by CETR and originally advanced by Rodeheaver. But for a multifilament having 12 fibers and total freedom of movement, as shown in the picture, the moment of inertia is  $12 \cdot \pi D_f^4 / 64$ . Accordingly, the monofilament's and multifilament's moment of inertia, and therefore their bending rigidity, are not equal. Because FiberWire is neither a monofilament nor a multifilament having complete independent fiber movement, its bending stiffness is somewhere between a monofilament and multifilament structure. Thus, assuming FiberWire is a monofilament, as Dr. Mukherjee and the CETR testing assume, also produces errors.

49. The third reason that I disagree that Dr. Mukherjee can draw conclusions from CETR's "pliability tests" is that CETR incorrectly assumes that the FiberWire samples have a circular cross section and that the diameter of each FiberWire suture is constant and equal to 0.65 mm. (Mukherjee Res. Report at Ex. 20 at 3). The Rodeheaver paper assumes a constant circular cross section. Dr. Mukherjee and CETR do not provide any basis for the assumption that the FiberWire samples have a constant circular cross section. The Rodeheaver paper also assumes a

constant diameter along the linear axis of the tested structure. Dr. Mukherjee and CETR do not provide any basis for the assumption that the tested FiberWire samples have a constant diameter along their linear axis. I have consulted with Dr. Matt Hermes. Based on his experience, he opined that even amongst the same USP size suture, suture diameters vary along their linear axis. I have reviewed the attached summary of Pearsalls' batch records, and they show variation in FiberWire's diameter for sutures made from same batch (Ex. AA). For example, the suture diameter varies between the "dye" (uncoated) and "intermediate" (coated) stages, as well as between the "intermediate" and "measure" stages. Thus, FiberWire varies in diameter, and it was incorrect for Dr. Mukherjee and CETR to assume that it does not. This error in assuming that the diameter is always the same is magnified to the fourth power because, in the monofilament equation used by Dr. Mukherjee, the diameter of the suture is raised to the fourth power (Ex. 20 of Mukherjee Res. Report at 3).

50. I also note that CETR's "pliability test" graph is not an accurate depiction of the tensile stress-strain relationship. CETR uses a non-linear, non-logarithmic scale on the horizontal axis. This distorts the true slope of the data. Also, I am not sure whether CETR reported all of its data in this graph or a portion of the data. I note that the data reported seems to be only part of a stress-strain curve that is obtained from a typical tension test. I know this because Figure 2 does not show the strain to failure of either of the samples.

51. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by his "knot slippage strength tests" and "knot run-down tests." I have consulted with Dr. Hermes and, from what we know about these tests, they are basically a type of tension test, similar to the "pliability" test conducted by CETR. Therefore, the slope of the curve from these tests before slippage or run down should be similar to that

obtained in CETR's "pliability" test. But they are not. During the pliability tests, CETR found that the coated suture had a lower modulus, as shown by its smaller slope (Mukherjee Res. Report at Ex. 20 at 3-4). In contrast, the other two CETR tests report a higher modulus for the coated suture, but it is not clear by how much from the graph and data (Mukherjee Res. Report at Ex. 20 at 5-8). The point being that the tests results are inconsistent. They appear to contradict the conclusions drawn by Dr. Mukherjee from the CETR "pliability" tests. Based on the limited information that I have about the tests, they are either inconclusive or show that coating has no material affect on tensile strength because the variations are due to the testing, not the material.

52. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by Pearsalls' testing. Ex. AA summarizes the results of Pearsalls' tension tests on batches of FiberWire at the "dye," "intermediate," and "measure" stages. Pearsalls found that FiberWire's tensile strength basically stayed the same between the uncoated FiberWire and FiberWire that underwent the coating processes. Although there are some variations in the reported measurements (*i.e.*, the tensile strength appears to go up, down, and stay the same), it is my opinion that these are really just an artifact of the testing (*i.e.*, operator variations, knot tying, or the expected variations inherent to textile testing) and not true variations (see paragraphs 40-41). I note that Dr. Mukherjee ignores these data in his analysis.

**(4) Dr. Mukherjee's "Drape" Test Is Flawed & Inconclusive**

53. I have considered Dr. Mukherjee's "drape test." This "test" is overly simplistic and flawed. Dr. Mukherjee states that he performed his drape test by "draping the suture over [his] extended index finger and observing the degree to which the suture conforms to the shape of [his] finger" (Mukherjee Res. Report at 27). First, I do not understand what he means by "conforms to the shape of my finger." Therefore, I cannot fully respond to his statement

because, among other reasons, I cannot tell what he measured. Second, it appears that Dr. Mukherjee is attempting to approximate FiberWire's pliability by determining FiberWire's ability to bend by using his finger as a test rig. But this method is flawed because he did not provide a true cantilever end support. Consequently, there is no defined position as to where FiberWire begins its bending, and no definitive way to determine the degree of bending. Third, diameter affects pliability, and Dr. Mukherjee does not provide any diameter measurements for the samples that he compared. Therefore, based on what I can determine from his report, it is not possible to scientifically compare the pliability of the uncoated and coated FiberWire using this method.

54. I note that Dr. Mukherjee relies on documents that refer to Ethicon and Mitek products in his analysis (Mukherjee Res. Report at 23-24, Mukherjee Res. Report Exs. 14, 15, 17, & 18). I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products.

**B. If Dr. Mukherjee Is Correct Regarding The Meaning Of The Novel And Basic Characteristics, TigerWire's Nylon Does Not Materially Affect Them**

55. Dr. Mukherjee has opined that TigerWire does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 30). I disagree for the reasons stated above with respect to FiberWire.

56. I understand that the differences between TigerWire and FiberWire are that TigerWire is not dyed blue and replaces one PET yarn strand with one black nylon yarn strand. Dr. Mukherjee opines that TigerWire's nylon materially affects pliability (Mukherjee Res. Report at 30-31). I disagree. The purpose of the nylon strand is for visual identification (Ex. V at 74:21-23). It is my opinion that replacing one PET yarn with one nylon yarn does not materially affect



the novel and basic characteristics of the claimed suture because the nylon marker does not prevent or materially affect FiberWire's PET and UHMWPE from being dissimilar, from being braided, or from being braided to have improved handleability and pliability without significantly sacrificing physical properties. I note that Dr. Mukherjee does not opine otherwise. Rather, he seems to opine that the nylon marker affects pliability. He does not address the issue of whether FiberWire's braid of dissimilar yarns with improved handleability and pliability performance without significantly sacrificing physical properties is affected.

57. Dr. Mukherjee states that TigerWire's nylon yarn "make[s] TigerWire stiffer" than FiberWire, and "materially" affects "pliability" (Mukherjee Res. Report at 31). He also states that "nylon 6,6 fibers of the type used in TigerWire are generally more stiff (*i.e.* less pliable) than fibers made of PET, as used in FiberWire and TigerWire" (Mukherjee Res. Report at 30). I again disagree. First, I disagree that generally TigerWire's nylon 6,6 fibers are necessarily stiffer than PET fibers. Dr. Mukherjee cites to his Ex. 26 for the principle that nylon is stiffer than PET. But Ex. 26 shows the comparative characteristics of "unfilled" PET and "molding compound" nylon. These are not the characteristics of fibers made from these polymers. Thus, it is my opinion that it is improper, absent further information, to rely on this molding compound data for fiber properties. Even if it were proper to rely on this data, Ex. 26 shows that PET has a flexural modulus of 350,000 psi to 450,000 psi and that nylon 6,6 has a flexural modulus of 410,000 psi to 470,000 psi. There is a significant overlap in these ranges. Based on this data, it is possible that nylon 6,6 fibers and PET fibers used in FiberWire and TigerWire have substantially the same flexibility. In that instance, the substitution of one nylon fiber for one PET fiber would have no substantial effect on the pliability of the braid. Second, even if the nylon and PET yarns have different flexibility, but the flexibility were still in the range cited in

Ex. 26, it is my opinion that replacing one nylon yarn with one PET yarn would not materially affect the suture's pliability because the two types of material are close enough in flexural modulus as to be essentially indistinguishable in the FiberWire braid. In fact, the one nylon yarn only makes up about 12% of the suture by weight (Ex. EE at ARM 14744).

58. Dr. Mukherjee's opinion that nylon 66 is generally more stiff than polyester is contradicted by *Marks' Standard Handbook for Mechanical Engineers* (Ex. J at Table 2 at p. 6-155). The elastic modulus of nylon 66 fiber ranges from 25 to 50 gpd and the elastic modulus for polyester fiber, which I read to include polyester, ranges from 50-80 gpd. Thus, it is indicated that nylon 66 fiber is *less stiff* than polyester.

59. My opinion that TigerWire's nylon does not materially affect TigerWire's pliability is supported by Arthrex's testimony. My. Dreyfuss from Arthrex testified that TigerWire and FiberWire show "very similar" knot strength, tensile strength, [and] handleability (Ex. V at 76:1-5). Also, Mr. Dreyfuss testified that that the nylon strand had only "minute" effects on the feel of the suture as compared to FiberWire (Ex. V at 75:13).

60. I understand that Dr. Mukherjee relies on a "drape" test comparing FiberWire and TigerWire. My comments and opinions about Dr. Mukherjee's "drape" test above apply here as well. Additionally, I do not understand what Dr. Mukherjee means when he says "to a much greater degree" and the "course [sic] feel would suggest that the addition of the nylon would adversely affect knot tie-down" (Mukherjee Res. Report at 31). Therefore, I cannot really respond to his opinion. Nevertheless, I understand that Dr. Hermes has considered both no. 2 TigerWire and FiberWire. I also understand that he could not determine any significant difference in the stiffness of TigerWire and FiberWire. Again, Dr. Mukherjee provides no diameter measurements for the samples, and diameter can affect pliability.

**C. If Dr. Mukherjee Is Correct Regarding The Meaning Of Novel And Basic Characteristics, The Adhesive As Used On Arthrex's FiberStick Product Does Not Materially Affect Them**

61. Dr. Mukherjee has opined that FiberStick does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 31-32). I disagree for the reasons stated above with respect to FiberWire. Dr. Mukherjee also states that FiberStick's adhesive materially affects "suture" handleability and therefore concludes that the adhesive materially affects the novel and basic characteristics, as he defines them. It is not my opinion that the adhesive materially affects the novel and basic characteristics, as they are defined by Dr. Mukherjee, because about 38 inches of FiberWire does not have adhesive. The adhesive is irrelevant to the portion of FiberStick's that has no adhesive. Because the portion of FiberStick that has no adhesive still infringes, there is no reason to even consider the adhesive.

62. Arthrex's intended use of FiberStick confirms my opinion that the portion of FiberStick that has adhesive is irrelevant to the properties of the portion that has no adhesive. As I understand FiberStick, it is about a 50 inch length of FiberWire that has about 12 inches of its length treated with Loc-Tite (Ex. FF at ARM1495 at 13-2 and Ex. V at 122:1-15). According to FiberStick's design history file, a portion of FiberStick is treated to "allow for suture loading" and for suture passing through cannulated instruments (Ex. GG at ARM7847). Further, according to Arthrex's intended use, once FiberStick has been passed through a cannulated instrument, the portion having adhesive "can then be cut leaving the remaining suture in place to perform repairs" (Ex. GG at ARM7848). In fact, after the Loc-Tite treated portion of FiberStick has been cut and disposed of, Arthrex promotes using FiberStick's untreated "suture" portion in the "fashion identical to that which is currently marketed" (Ex. GG at ARM7850). The remaining suture is simply a FiberWire suture. As Arthrex states, the treated end does not "affect the design" of the suture (Ex. GG at ARM7848) or "change the intended use or

indication” (Ex. GG at ARM7850). The adhesive portion is only for suture placement; it does not affect the remainder of the suture. Thus, Arthrex’s intended use for FiberStick confirms my opinion that the adhesive has no material effect on the portion of FiberStick that does not have adhesive.

## **V. Reverse Doctrine of Equivalents**

63. I have been asked to opine on the issue of whether the reverse doctrine of equivalents applies to FiberWire. Based on discussions with counsel, I understand that the reverse doctrine of equivalents applies when an accused product literally contains all the elements of a claim, but the product is so far changed in principle that it performs the function of the claimed invention in a substantially different way. It is my opinion that the reverse doctrine of equivalents does not apply because FiberWire is not so far changed in principle from the suture claimed in the 446 Patent. I disagree that FiberWire is so far changed in principle that it performs the function of the claimed invention in a substantially different way for the reasons explained above with reference to the doctrine of equivalents (*see* Section III).

## **VI. FiberWire’s Success Is Not Due To Just FiberWire’s UHMWPE**

64. Dr. Mukherjee opines that he disagrees with my opinion that “some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the ‘446 Patent” (Mukherjee Res. Report at 33). According to Dr. Mukherjee, the “superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE” (Mukherjee Res. Report at 34). I disagree with Dr. Mukherjee’s statement. Dr. Mukherjee’s statement is contradicted by Arthrex’s own marketing documents, technical documents, and technical witnesses.

65. I also disagree with Dr. Mukherjee because he ignores all of the benefits advanced by Arthrex in Arthrex’s marketing literature. For example, he ignores that Arthrex promotes that

FiberWire's "polyester braided jacket . . . gives FiberWire superior strength" and it promotes FiberWire as a "braided polyblend suture" (Mukherjee Res. Report at Ex. 30). He further ignores that Arthrex touts other properties such as "knot slippage," knot profile" to name a few, which can be attributed to the claimed heterogeneous braid (Mukherjee Res. Report at Ex. 30) for the reasons provided below.

66. Mr. Grafton, developer of Arthrex's FiberWire, testified that the increase in strength of FiberWire is not due to UHMWPE. Mr. Grafton testified that a 100% UHMWPE braided suture was unacceptable because the knot holding strength was too low (Ex. I at 46:7-15; 52:16-20). Mr. Grafton said that the knot holding strength was too low because of the lubricity of the UHMWPE. Mr. Grafton then had the idea of adding PET into the braided structure, so that the PET would increase the knot holding strength (Ex. I at 53:8-11; 54:9-14). It was not until Arthrex braided the UHMWPE with PET that the "polyblend" suture became acceptable (Ex. I at 54:9-55:15).

67. Mr. Grafton also represented to the Patent Office that UHMWPE alone was not acceptable in suture applications because the knot tie down or knot security was too low (Ex. I at 24:18-21; 103:25-104:12; Ex. R). Based on these statements from Mr. Grafton, I disagree with Dr. Mukherjee when he states that "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE." Rather, FiberWire's benefits touted by Arthrex can be attributed at least in part to the invention claimed in the 446 Patent.

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

A handwritten signature in black ink, consisting of a stylized 'D' followed by a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.  
Fellow-American Society of Mechanical Engineers



**CERTIFICATE OF SERVICE**

I certify that the foregoing Rebuttal Expert Report of Dr. David Brookstein was served by Federal Express overnight mail on April 13, 2006 on the following:

Charles W. Saber  
Dickstein, Shapiro, Morin & Oshinsky, LLP  
2101 L. Street, NW  
Washington, DC 20037-1526.

Christopher Weld, Jr.  
Todd & Weld LLP  
28 State Street, 31<sup>st</sup> Floor  
Boston, MA 02109

Dated: April 13, 2006

  
\_\_\_\_\_  
Rich M. Falke

# **EXHIBIT 25**

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3 C.A. NO. 04-12457 PBS

4 \_\_\_\_\_ x  
5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.  
12 \_\_\_\_\_ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18  
19  
20 Reported by:

21  
22 PAMELA HARRISON, RMR, CRR, CSR  
23  
24  
25

**TRAVEL  
TRANSCRIPT**